Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K111717 - 285 pages
COMPANY:	ELECTRO-CAP INTL., INC. (ELECCAP)
PRODUCT:	MEDIA, ELECTROCONDUCTIVE (GYB)
SUMMARY:	Product: ELECTRO-GEL
DATE REQUESTED:	Aug 15, 2014
DATE PRINTED:	Aug 15, 2014
Note:	Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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JAN - 5 2012

K111717

510K summary

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact:	Amy Swallows
Phone:	937-456-6099
Fax:	937-456-7323
Summary Date:	June 15, 2011 (Revised December 30, 2011)
Trade Name:	Electro-Gel
Common Name:	Electrode Gel
Classification Name:	Media, Electroconductive
Regulation Number:	21 CFR 882.1275
Product Code:	GYB

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Electro-Gel is an off white color, water-miscible conductive gel consisting of Sodium Chloride as the conductor combined with thickening agents, emulsifiers, humectants and preservatives all in an aqueous solvent.
The formula is as follows:

Water	Potassium Bitartrate
Aragum T-1998	Sodium Chloride
Methylparaben	Propylparaben
Glycerin	

The pH range is 4.5 to 6.0 pH, Viscosity range is 575 to 615 cp. and Impedance 0.5K/Ohms or less.
Direct contact with the Electro-Gel should not exceed 8 hours in any single recording session.
The Electro-Gel is available in the following jar sizes: 16 ounce, 32 ounce and 128 ounce. Shelf life is 1 year if stored properly, i.e. kept with containers tightly closed and at room temperature.

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Predicate Comparison

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

(Please refer to the comparison tables on the following four pages).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 1 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 1: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.	K111717	K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 2. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 2: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.	K111717	K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, impedance and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 5 2012

Electro-Cap International, Inc.
c/o Ms. Amy Swallows
Director of Marketing
1011 West Lexington Road
Eaton, OH 45320

Re: K111717
Trade/Device Name: Electro-Gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: December 19, 2011
Received: December 20, 2011

Dear Ms. Swallows:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment B

Indications for Use

510(k) Number (if known): K111717

Device Name: Electro-Gel

Indications for Use:

Electro-Gel is intended for use in clinical and research EEG/EP recordings from humans. It is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Grimes

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111717

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K111717/~~57~~ A1

Electro-Cap International, Inc.

August 15, 2011

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
US Food and Drug Administration

FDA CDRH DMC
AUG 16 2011
Received

Re: K111717

Dear Ms. Aguel,

We are writing in response to your letter dated 7/28/11, with regards to our 510(k) filing for Electro-Gel. We are submitting the following information so that the review of our submission may be completed.

1. Device description

   A. The specific concentrations of ingredients are as follows:

(b)(4) [redacted]

(b)(4) [redacted]

2. Device testing

(b)(4) [redacted]

1011 West Lexington Road • P.O. Box 97 • Eaton, Ohio 45320 • 1-800-327-2133 • 937-456-6099 • FAX 937-456-7323

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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3. Device testing

You will find attached our design specifications for pH, viscosity, conductivity and ingredient mixture, along with our certification statement that the gel has been tested and meets these specifications.

4. Labeling

Attachment C has been revised to incorporate the requested information.

5. Administrative

We have revised the 510(k) summary as requested and attached it with this correspondence.

A. We have updated our original predicate device table, and have added a second table which includes the additional predicates as requested.

B. We have added a section for Device Testing in our summary. We have noted in the summary (as mentioned previously) that we have arranged for independent testing. We will revise the summary when we have received those test results.

C. We have added the device description information as requested.

6. We have downloaded the certificate, and will be able to complete it and send it to you with the results of the testing when that testing has been completed.

7. We have reviewed the information regarding electronic submissions.

As noted previously, we should have the independent test results for biocompatibility in eight to ten weeks. Accordingly, we are requesting an extension of 90 days in order that we may have an opportunity to submit the test results as an addition to our original submission. Please let us know if we need to submit a separate request for an extension.

If you have further questions, or need additional information, please do not hesitate to contact us.

Best regards,

Amy Swallows

Amy Swallows
Director of Marketing
Electro-Cap International, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

eci

ELECTRO-CAP INTERNATIONAL, INC
1011 W. Lexington Rd., Eaton, OH, 45320, USA
TEL: 937 456-6099 FAX: 937 456-7323 email: eci@electro-cap.co

ELECTRO-GEL CERTIFICATION

The current (after July 2008) formula of Electro-Gel has been, and is, tested for viscosity, pH, and conductivity. Electro-Gel meets all of the requirements listed below. These requirements are in accordance with the design specifications for this product.

	Acceptable Range
Viscosity:	575 to 615 cp
Conductivity:	0.5 kΩ or less
pH:	3 – 7 pH
Ingredients Mixture:	Manufacturing Procedure Attached

Amy Swallows 8/11/11
Amy Swallows
Electro-Cap International, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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MANUFACTURING PROCEDURE
GEL

(b)(4)

[redacted]

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment C

Device Labeling

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment E
510K summary

Company Name: Electro-Cap International, Inc.
1011 West Lexington Road
P.O. Box 87
Eaton, OH 45320

Contact: Amy B. Swallows
Phone: 937-456-6099
Fax: 937-456-7323

Summary Date: June 15, 2011 (rev.1 8/11/11)

Trade Name: Electro-Gel

Common Name: Electrode Gel

Classification Name: Media, Electroconductive

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: Ten20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics
Trade Name: Quik Gel

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

5.0 Conclusions

The intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised. The Electro-Gel will perform as well as the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.		K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates
Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes (Testing in progress)	Yes	Yes	Same as predicates
Irritation	Yes (Testing in progress)	Yes	Yes	Same as predicates
Sensitization	Yes (Testing in progress)	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Table 4.0. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.		K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Record processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates
Biocompatibility	Test in accordance with ISO 10993	Yes	Yes	Same as predicates
Cytotoxicity	Yes (Testing in progress)	Yes	Yes	Same as predicates
Irritation	Yes (Testing in progress)	Yes	Yes	Same as predicates
Sensitization	Yes (Testing in progress)	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

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Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016

K111717 A2

Electro-Cap International, Inc.

FDA CDRH DMC

NOV 23 2011

Received

November 22, 2011

Mr. John Grimes
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: 510K Summary for K111717

Dear Mr. Grimes,

You will find enclosed two copies of our revised 510K Summary for Electro-Gel. If you have any questions, or need additional information, please do not hesitate to contact us.

Best regards,

Amy Swallows

Amy Swallows
Director of Marketing
Electro-Cap International, Inc.

1011 West Lexington Road • P.O. Box 97 • Eaton, Ohio 45320 • 1-800-327-2199 • 937-456-6099 • FAX 937-456-7323

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

510K summary

Company Name: Electro-Cap International, Inc.
1011 West Lexington Road
P.O. Box 87
Eaton, OH 45320

Contact: Amy Swallows
Phone: 937-456-6099
Fax: 937-456-7323

Summary Date: June 15, 2011 (Revised November 9, 2011)

Trade Name: Electro-Gel

Common Name: Electrode Gel

Classification Name: Media, Electroconductive

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Electro-Gel is an off white color, water-miscible conductive gel consisting of Sodium Chloride as the conductor combined with thickening agents, emulsifiers, humectants and preservatives all in an aqueous solvent. The pH range is 3 - 7 pH. It is available in the following jar sizes: 16 ounce, 32 ounce and 128 ounce.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Predicate Comparison

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

(Please refer to the comparison tables on the following four pages).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.	K111717	K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

108

Table 4.0. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.	K111717	K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/DCE/DID at CDRH-FOISTATES@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, conductivity and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

K30

Electro-Cap International, Inc.

K111717 / ~~A2~~ A3

FDA CDRH DMC
DEC - 1 2011
Received

November 30, 2011

Mr. John Grimes
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: 510K Summary for K111717

Dear Mr. Grimes,

As discussed in our email earlier today, you will find enclosed two copies of our revised 510K Summary for Electro-Gel. If you have any questions, or need additional information, please do not hesitate to contact us.

Best regards,

Amy Swallows

Amy Swallows
Director of Marketing
Electro-Cap International, Inc.

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1011 West Lexington Road • P.O. Box 97 • Eaton, OH 45320 • USA • Phone 937-456-7099 • FAX 937-456-7323
Questions? Contact DM/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or call 301-796-9118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

510K summary

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact:	Amy Swallows
Phone:	937-456-6099
Fax:	937-456-7323
Summary Date:	June 15, 2011 (Revised November 30, 2011)
Trade Name:	Electro-Gel
Common Name:	Electrode Gel
Classification Name:	Media, Electroconductive
Regulation Number:	21 CFR 882.1275
Product Code:	GYB

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Electro-Gel is an off white color, water-miscible conductive gel consisting of Sodium Chloride as the conductor combined with thickening agents, emulsifiers, humectants and preservatives all in an aqueous solvent. The pH range is 3 - 7 pH. It is available in the following jar sizes: 16 ounce, 32 ounce and 128 ounce.

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Predicate Comparison

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

(Please refer to the comparison tables on the following four pages).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.	K111717	K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 4.0. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.	K111717	K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, conductivity and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 5 2012

Electro-Cap International, Inc.
c/o Ms. Amy Swallows
Director of Marketing
1011 West Lexington Road
Eaton, OH 45320

Re: K111717
Trade/Device Name: Electro-Gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: December 19, 2011
Received: December 20, 2011

Dear Ms. Swallows:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Attachment B

Indications for Use

510(k) Number (if known): K111717

Device Name: Electro-Gel

Indications for Use:

Electro-Gel is intended for use in clinical and research EEG/EP recordings from humans. It is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Grimes

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111717

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Williams, Michael *

From: Microsoft Outlook
To: 'aswallows@electro-cap.com'
Sent: Monday, December 19, 2011 2:47 PM
Subject: Relayed: K111717-Hold Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'aswallows@electro-cap.com'

Subject: K111717-Hold Letter

Sent by Microsoft Exchange Server 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 19, 2011

ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS

510k Number: K111717
Product: ELECTRO-GEL
On Hold As of 12/16/2011

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Redacted Safe Medical Devices Act FOIA Request #2015-907 - Released by CDRH on 03-07-2016

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 18, 2011

ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS

510k Number: K111717

Product: ELECTRO-GEL

Extended Until: 11/25/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Electro-Cap International, Inc.

FDA CDRH DMC
AUG 17 2011
Received K5

August 16, 2011

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
US Food and Drug Administration

RE: K1111717

Dear Ms. Aguel,

This is in response to your letter dated 7/28/11, with regards to our 510(k) filing for Electro-Gel. We have requested biocompatibility testing on our gel, but the test results will not be available for 8 – 10 weeks. Accordingly, we are requesting an extension of 90 days for the submission of the additional information requested so that the review of our premarket notification may be completed.

Please let us know if you need any further information at this time.

Best regards,

Amy Swallows
Electro-Cap International, Inc.

1011 West Lexington Road • P.O. Box 97 • Eaton, OH 45320 • 937-456-7698 • 800-872-2183 • 937-456-7698. FAX 937-456-7323

Questions? Contact FDA/CDRH/OCE/ODE at 301-796-5640 or CDRH-FOIA-STATUS@fda.hhs.gov

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Electro-Cap International, Inc.

eci

FDA CDRH DMC
AUG 17 2011
Received

August 16, 2011

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
US Food and Drug Administration

RE: K1111717

Dear Ms. Aguel,

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Please let us know if you need any further information at this time.

Best regards,

Amy Swallows

Amy Swallows
Electro-Cap International, Inc.

1011 West Lexington Road • P.O. Box 87 • Eaton, Ohio 45320 • 1-800-527-2193 • 937-456-6099 • FAX 937-456-7323
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Nichols, Karl *

From: Microsoft Exchange
To: 'aswallows@electro-cap.com'
Sent: Tuesday, August 16, 2011 5:06 PM
Subject: Relayed: K111717- AI letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'aswallows@electro-cap.com'

Subject: K111717- AI letter

Sent by Microsoft Exchange Server 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 16, 2011

ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS

510k Number: K111717

Product: ELECTRO-GEL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 01, 2011

ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS

510k Number: K111717
Product: ELECTRO-GEL

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

Records processed under FOIA request #2015-3531, release date 01-29-2016

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 21, 2011

ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS

510k Number: K111717
Received: 6/20/2011
Product: ELECTRO-GEL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissio /PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: **MD6056224-956733**
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ELECTRO CAP INTERNATIONAL INC
1011 W LEXINGTON RD
EATON OH 45320
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****4202

2. CONTACT NAME
WILLIAM HARDIN

2.1 E-MAIL ADDRESS
nhardin@electro-cap.com

2.2 TELEPHONE NUMBER (include Area code)
937-4566099

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
937-4567323

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
$4,348.00 14-Jun-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/15/2011	MD6056224-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Electro-Cap International, Inc.	Establishment Registration Number *(if known)*: 1626185		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 937-456-6099		
Street Address: 1011 W. Lexington Road	FAX Number *(including area code)*: 937-456-7323		
City: Eaton	State / Province: Ohio	ZIP/Postal Code: 45320	Country: USA
Contact Name: Amy B. Swallows			
Contact Title: Director of Marketing	Contact E-mail Address: aswallows@electro-cap.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Graphics: (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [x] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GYB	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K780045	1	Electro-Gel (Prior July 2008)	1	Electro-Cap International, Inc.
2	K883149	2	TEN20 Conductive Paste	2	Weaver and Company
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Electrode Gel - Media, Electroconductive

	Trade or Proprietary or Model Name for This Device		Model Number
1	Electro-Gel	1	E9, E10, E11
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: GYB

C.F.R. Section *(if applicable)*:

Classification Panel:

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

Electro-Gel is intended for use in clinical and research EEG/EP recordings from humans. It is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 31-1234202	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☒ Repackager / Relabeler		
Company / Institution Name: Electro-Cap International, Inc.		Establishment Registration Number: 1626185		
Division Name *(if applicable)*		Phone Number *(including area code)*: 937-456-6099		
Street Address: 1011 W. Lexington Road		FAX Number *(including area code)*: 937-456-7323		
City: Eaton		State / Province: Ohio	ZIP Code: 45320	Country: USA
Contact Name: Amy B. Swallows	Contact Title: Director of Marketing		Contact E-mail Address: aswallows@electro-cap.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	21CFR Part 800	FDA	Medical Devices		
2	ISO 9000:2007	IEC Standards	Quality Management Systems		01/01/2007
3	ISO 13485:2003	IEC Standards	Medical Devices - Quality management systems - Requirments for regulatory purposes		01/01/2003
4	93/42/EEC	Standards Organization IEC Standard	Medical Devices Directive 93/42/EEC	MEDDEV 2.12.1 rev 4	01/01/2001
5	ISO 14971:2007	IEC Standards	Medical Devices - Application of Risk Management to Medical Devices		01/01/2007
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Company Name Electro-Cap International, Inc.
Product Electro-Gel
Type Traditional510(k) Pre-Market Notification Elements List

510(k) Elements	Submission Location
Cover letter	Cover Letter
Table of Contents	Table of Contents
Truthful and Accurate Statement	Section 2.0
Device Trade Name, Device Classification Name and Establishment Registration Number	Cover Letter - Items 2,3 & 4
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Cover Letter - Item 5
Proposed Labeling	Attachment C
Statement of Indications for Use	Attachment B
Substantial Equivalence Comparison, comparisons of the new device with the predicate.	Section 4.0
510(k) summary	Attachment E
Description of the device (or modification of the device). Identification of legally marketed predicate device.	Section 1.0 Cover Letter - Item 7
Compliance with performance standards.	Cover Letter - Item 9
Class III certification and Summary.	Not Applicable (NA), not a Class III Device.
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study.	NA - No sponsored clinical study.
510(k) Kit Certification	NA - Not a kit.
Additional Traditional 510(k) Elements	**Submission Location**
Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation.	Section 7.0
Sterilization and expiration dating information	Section 6.0.
Software Documentation	NA - No software.
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type.	Sections 6.0, 8.0
For a submission, which relies on a recognized standard, a declaration of conformity.	Section 8.0
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA. Recognized Standard conformance declared.
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA. Recognized Standard conformance declared.
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.	NA. Recognized Standard conformance declared.
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.	NA. Recognized Standard conformance declared.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Electro-Cap International, Inc.

Electrode Gel

Traditional 510(k) Pre-Market Notification

510(k) Table of Contents

Section	Title	Page
	MDUFMA User Fee Cover Sheet	Not Applicable
	CDRH Submission Cover Sheet	NA
	510(K) Elements Checklist	NA
	Cover Letter	CL-1
1.0	Device Description	1
2.0	Truthful and Accurate Statement	4
3.0	Labeling	5
4.0	Specifications/Comparisons to Predicate Devices	6
5.0	Risk/Hazard Analysis	7
6.0	Sterility	7
8.0	Biocompatibility	7
8.0	Standards Conformance	8
Attachment A	Reference Articles	A-1
Attachment B	Indications For Use Form	B-1
Attachment C	Device Labeling	C-1
Attachment D	Predicate Device Labeling	D-1
Attachment E	510(k) Summary	E-1
Attachment F	Electro-Gel Risk Analysis	F-1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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June 15, 2011

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC
JUN 20 2011
Received

Re: Traditional 510(k) Application
Electro-Gel – Media, Electroconductive

The enclosed Traditional 510(k) Application is submitted in compliance with 21 CFR 807. The purpose of this submission is to show that Electro-Cap International Inc.'s Electro-Gel (EEG conductive gel) which has been marketed for the past 23 years is substantially equivalent to the Electro-Gel (EEG conductive gel) which received 510(k) clearance in 1978 (K780045).

This 510(k) submission is made in response to an observation from an FDA investigator, Brigitte K. Hofmann on Form FDA 483, Inspectional Observations, dated 04/28/2011, who recommended we do so in order to adequately document to the FDA the changes which were made to the formulation. Given the fact that the amount of the 2008 formulated Electro-Gel, that has been sold, was enough to record more than 10,000,000 EEG's, with in the United States and 120 foreign countries with only one known minor incident reported, we maintain that this submission is very straight forward.

In support of this position, the following information is provided for reference.

Applicant Name: Electro-Cap International, Inc.

1. Submission Correspondent: Amy B. Swallows
2. Trade Name: Electro-Gel
3. Common Name: Electrode Gel
4. Manufacturing Site Address: Electro-Cap International, Inc.
   1011 West Lexington Road,
   Eaton, OH 45320
5. These devices are manufactured by: Electro-Cap International, Inc.
6. Establishment Registration Number: 1626185
7. Classification Name: Media, Electroconductive
8. Product Code: GYB
9. Predicate: Electro-Cap International Inc.s "Electro-Gel" and Weaver and Company's TEN20 Conductive Paste have been found substantially equivalent to Electro-Gel. 21 CFR 882-1275, Class ll Product Code: GYB
10. Reason for Traditional 510(k): Adequately document to the FDA changes made to the formulation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

11. Predicate Device(s):

510(k) Number:	K780045
Manufacture:	Electro-Cap International, Inc.
Trade Name:	Electro-Gel
Product Code:	GYB
Classification:	Media, Electroconductive

510(k) Number:	K883149
Manufacture:	Weaver and Company
Trade Name:	TEN20 Conductive Paste
Product Code:	GYB
Classification:	Media, Electroconductive

12. Compliance to Special Controls: There are no known special controls which apply to this device.

13. Performance Standards: There are no known performance standards which apply to this device. A list of the quality standards to which the company complies with is attached.

Contact information:
Amy B. Swallows
Electro-Cap International, Inc.
PO Box 87, Eaton, OH 45320
Tel: 937-456-6099
Fax: 937-456-7323
Email: aswallows@electro-cap.com

Sincerely,

Amy B. Swallows,
Director of Marketing
Electro-Cap International, Inc.

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

1.0 DEVICE DESCRIPTION

1.1 Basic Description of Device:

Electro-Gel is an off white color, water-miscible conductive gel intended for use with the Electro-Cap and other non-disposal neurodiagnostic electrodes including ECG and EMG electrode applications. It is water soluble and can be easily and completely washed from the head with water and shampoo.

Electro-Gel serves as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the electroencephalogram or computer equipment. Electro-Gel is for use with external electrodes only.

Electro-Gel should be used topically on healthy, intact skin only. It should not be used on or near open wounds, bruised or weakened skin due to injury or the medical condition of the patient. It should not be used on patients with a history of skin allergies or sensitivity to cosmetics and lotions. If rash, redness, itching, swelling, or abnormality appears on skin, wash off immediately. Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites.

Electro-Gel is a mixture of the following components: Water, Sodium Chloride, Aragum T-1998 (Gum Acacia, Guar Gum, and Xanthan Gum), Potassium Bitartrate (Cream of Tartar), Glycerin, Methylparaben and Propylparaben.

Component specifications:

a) Water: Tap water. Function is vehicle.
b) Sodium Chloride: Morton's culinox 999 chemical grade salt. Function is conductance.
c) Aragum T-1998 Powder: Gum Acacia, Guar Gum and Xanthan Gum. Function is viscosity.
d) Potassium Bitartrate: (Cream of Tartar), Powder NF/FCC. Function is to improve electrode contact.
e) Glycerin: Glycerine 99.7% USP Kosher. Function is humecant, preservative and viscosity.
f) Methylparaben: NF. Function is preservative.
g) Propylparaben: USP. Function is preservative.

1.2 Background:

Electro-Gel was developed for use with the Electro-Cap and introduced to the market in 1978. The Electro-Cap, an improved method of rapid application of EEG electrodes, contained one of the first recessed electrodes used for EEG. The Electro-Gel was developed specifically to remain in contact with the scalp and the recessed electrode with mechanically stable 1-3 kohms impedance. The inventor received an international award for the ECI Electro-Cap System from the International Federation of Societies of EEG and Clinical Neurophysiology in 1981. Electro-Cap International, Inc. of Eaton, Ohio purchased the company in 1988.

The Electro-Gel was manufactured with the same formula received with the purchase of the company until 1991 when the preservatives, Methylparaben and Propylparaben, replaced Phenol.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The original formula contained Tragacanth, a water –soluble carbohydrate gum used as a thickening and stabilizing agent. Tragacanth is harvested from plants in Iran and the Middle East and due to troubled diplomatic relations it became very difficult to obtain a steady supply. Accordingly, other gums such as Aragum T-1998 have replaced Tragancanth in food, cosmetic and drug products and was selected by Electro-Cap as the replacement for Tragacanth in 2008.

Prior to releasing the new formula to the market it was tested in hospitals in the United States and several hospitals in The Netherlands for several months. All reports indicated that the gel was better than the previous gel with no problems with viscosity or conductance and no reported adverse skin or eye reactions.

The amount of 2008 formulated Electro-Gel that has been sold would be enough to use in recording over 10,000,000 EEGs. This formula has been used by The National Institute of Health, in research laboratories around the world, and by researchers on the International Space Station.

1.3 Device Technology:

The Electro-Gel is the conductor between the scalp and the (recessed) electrodes. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment.

When the Electro-Cap or other recessed electrodes are placed on the head the Electro-Gel is inserted into the electrode mount cavity by using a 16 gauge blunted needle and a 5cc syringe. With other types of electrodes, it is used according to accepted techniques.

1.4 Application:

Electro-Gel is used under the supervision of a physician, EEG technologist, radiologist or other trained medical professionals.

Attachment A contains reference articles with regard to clinical use of Electro-Gel and supports the use of Electro-Gel.

1.5 Indications for Use:

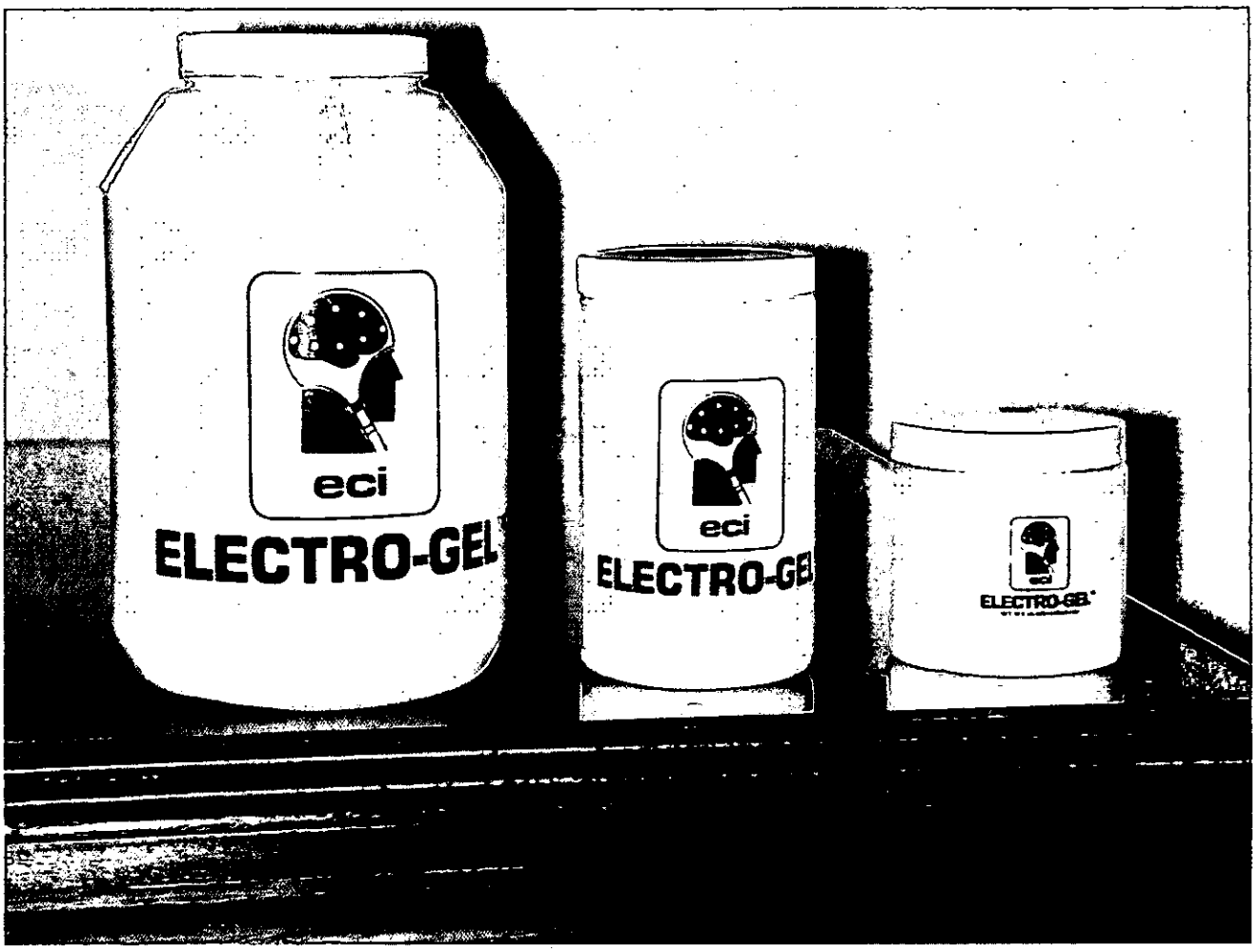
The indication for use for the Electro-Gel is consistent with the classification 21CFR 882.1275 namely Media, Electroconductive. The predicate device, Electro-Gel, was submitted as a part of the Electro-Cap System VII under 21 CFR 882.1320.

The FDA Indications For Use form is found as Attachment B.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

1.6 Electro-Gel E11, E10, E9



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

2.0 TRUTHFUL AND ACCURATE STATEMENT

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87 (j))

I certify that, in my capacity as Director of Marketing of Electro-Cap International Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Amy B Swallows
(Signature)

Amy B. Swallows,
Director of Marketing
Electro-Cap International, Inc.
(Printed Name, Title)

June 15, 2011
(Dated)

[Premarket Notification (510(k)) Number]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

2.0 LABELING

2.1 Proposed Labeling

Attachment C presents the proposed "DIRECTIONS FOR USE AND CAUTIONARY STATEMENT" for Electro-Gel. This statement will be provided with each container of gel shipment until this information can be printed on the gel jars. In order to satisfy Marketing needs, the specific layout is subject to change, along with font choices, etc., are subject to change, but the material contect of the labeling will not.

2.2 Predicate device labeling

The predicate device labeling is also provided in Attachment D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

3.0 SPECIFICATIONS/COMPARISONS TO PREDICATE DEVICES

Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicate (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	**Prior to July 2008** Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel has the same/equivalent Indication for Use as predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	NaCl	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	unknown	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Identical Preservative as predicates

3.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate Prior "July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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4.0 RISK/HAZARD ANALYSIS

4.1 ISO-14971 Compliant Analysis

Attached as "Exhibit F "is the Electro-Gel Risk Analysis recently conducted following the guidelines of ISO 14971. Because of simple nature of the device, the analysis itself is extremely simple.

4.2 Additional Risk Analysis

Also consider that the Electro-Gel is made from known biocompatible (food grade) materials. The only known instance of bioincompatibility involved one 5 month old pediatric patient in 2011 who suffered minor skin abrasions when the EEG test lasted for 24 hours. The two electrode sites on the back of the scalp, where pressure would have been applied while the child was on its back, were the only 2 of 10 sites affected. It was suggested to our distributor in Japan that the probable cause was the long exposure to the sodium chloride in the gel. The distributor agreed and the customer complaint was closed.

No other confirmed reaction to the gel has been recorded during the past 23 years.

Given the fact that the amount of the 2008 formulated Electro-Gel, that has been sold, was enough to record more than 10,000,000 EEG's, within the United States and 120 foreign countries with only one known minor incident reported (5 month child noted above), we maintain that this product is safe and efficacious for its intended use.

5.0 STERILITY

NOT APPLICABLE.

The product is not sold sterile, nor is there a clinical need for it to be supplied sterile.

6.0 BIOCOMPATIBILITY

The Electro-Gel is made from known biocompatible (food grade) materials. The only known instance of bioincompatibility involved one 5 month old pediatric patient in 2011 who suffered minor skin abrasions when the EEG test lasted for 24 hours. The two electrode sites on the back of the scalp, where pressure would have been applied while the child was on its back, were the only 2 of 10 sites affected. It was suggested to our distributor in Japan that the probable cause was the long exposure to the sodium chloride in the gel. The distributor agreed and the customer complaint was closed.

No other reaction to the gel has been recorded during the past 23 years the Electro-Gel has been used.

As such, we maintain that the biocompatibility of the product has been strongly demonstrated and we maintain that formal testing to ISO 10993-1 would add no value.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7.0 STANDARDS CONFORMANCE

There are no known formal performance standards which apply to the product, but we maintain that the efficacy of the product for its intended use has been demonstrated in the market place, and Electro-Gel's dominant market share. The amount of the 2008 formulated Electro-Gel that has been sold was enough to record more than 10,000,000 EEG's with only one known minor incident reported would also support this claim.

The following comments are also provided as a means of clarification:

Contact Duration

A clinical EEG test will last approximately two hours however brain monitoring during surgery last for several hours. The Electro-Gel is also used in sleep studies for up to 8 hours. There have no reported incidents of adverse skin reaction in any of these situations. Accordingly the contact duration would be in excess of 8 hours.

Electrical Performance

The conducting agent of the gel is Sodium Chloride with a ratio of 30 pounds dissolved in 40 gallons of water has been used for more than 30 years. During this period there has never been a customer complaint concerning the conductivity of the gel.

Stability

Shelf life is 2 years, provided the gel is stored in the original container at room temperature with the lid tightly closed.

7.1 Quality Standards Applied

Electro-Gel is manufactured in a facility which in in compliance with the following standards:

- Title 21 CFR part 800: Medical Devices
- Medical Devices Directive 93/42/EEC
- ISO 13485:2003 Medical Devices – Quality management systems
- ISO 9000:2007 Quality Management Systems
- ISO 14971:2007: Medical Devices – Application of Risk Management to Medical Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Attachment A

Electro-Gel has been cited in numerous peer-reviewed journal articles. The articles below are included because of their focused attention on the products.

esa **Multimedia Gallery**

European Space Agency

Search results:

18 results found

Keyword: neurospat

Caption:

Gel injections on the scalp for Neurospat

Credits:
ESA/NASA

ID number:
SEM39B1RJHG

HI-RES JPEG size:
377 kb

Related Images:
Astronauts
ISS and other space stations
MagISStra (Astronaut Nespoli)

Description

Cady Coleman inserting conductive gel to the EEG-capturing scalp of the Neurospat experiment. The Neurospat is a study of spatial cognition, novelty processing and sensorimotor integration, composed of two principal experimental tasks: visual orientation and visuomotor tracking, plus additional, standardized electroencephalogram (EEG) tasks performed as a means of assessing general effects of the space station environment on EEG signals.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Approaches to Quantitative EEG Analysis

The first step in QEEG analysis is the acquisition of a high fidelity analog cerebral biopotential; therefore an absolutely essential ingredient is the availability of the original analog EEG waveform or its digitized representation for quality assurance.[7] The electronically hostile environment of the operating room also requires flexible signal conditioning for QEEG analyzers in order to adapt to a wide range of circumstances. In particular, frequency components as low as 0.5 Hz must pass unaltered through the sampling, digitization, and filtering processes. Additionally, the influence of common sources of surgical artifact should be minimized by automatic artifact detection/rejection systems. The most useful systems afford a high degree of custom tailoring by the monitoring specialist which is necessary to meet the rapidly changing conditions encountered during surgery.

The AAN recommends that 8 to 16 channels be utilized for intraoperative EEG monitoring although four channels are considered to be the absolute minimum. Our experience places us in total agreement with this recommendation. The cerebrocortical mantle does not respond in homogenous fashion to suboptimal perfusion. EEG evidence of focal ischemia may be evident in only a single channel from the conventional 19-channel monopolar (referential) or 8-channel bipolar EEG montages. Fortunately, obtaining such detailed information may be greatly simplified through the use of commercially available nylon helmets[3] (see figure 1) that fix the scalp electrodes in the international 10-20 placement system (see figure 2).

The analog EEG waveform is nothing more than a graph of the voltage (ordinate) expressed as a function of time (abscissa). Quantitative displays that retain this time domain representation are important as they form a bridge between conventional EEG analysis and the more abstract frequency domain presentations described below. Computerized time domain analyses may increase the information content of EEG signals by data compression. Clinically significant changes in amplitude and/or frequency over long time periods can be compactly graphed as changes in univariate amplitude and/or frequency descriptors.

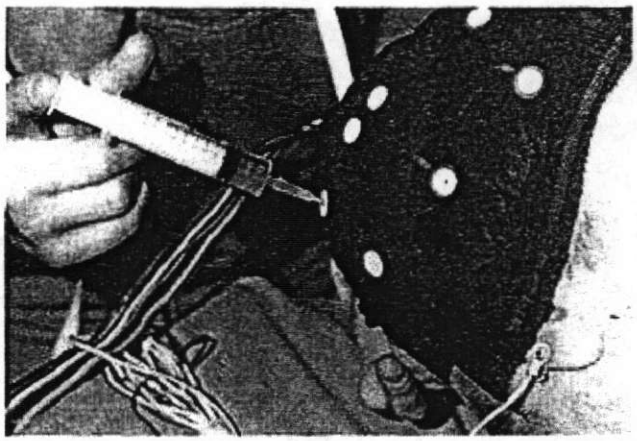

Figure 1. For intraoperative EEG recording, the electrodes are held in place using a nylon helmet. Conductive gel is placed in each plastic reservoir to ensure a high quality electrical connection with the scalp below. With this technique, the scalp-electrode impedance can be maintained below 5 Kohms for many hours. Also note the ear clip electrodes used for referential recording.

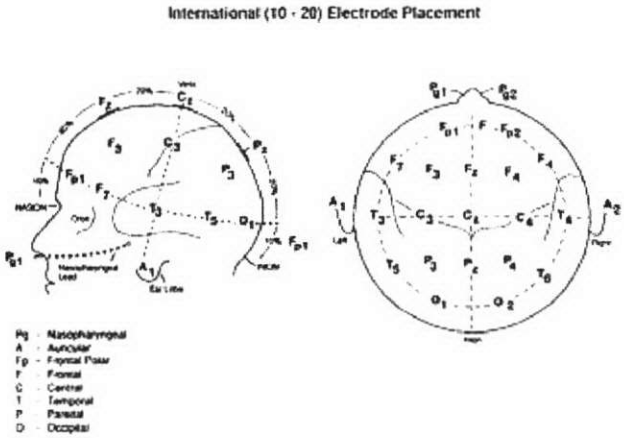

Figure 2. EEG electrode nomenclature and placement using the international 10-20 system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Attachment B

Indications for Use

510(k) Number (if known): _____

Device Name: Electro-Gel

Indications for Use:

Electro-Gel is intended for use in clinical and research EEG/EP recordings from humans. It is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment C

Device Labeling

Electro-Gel A0001 5/11

DIRECTIONS FOR USE AND CAUTIONARY STATEMENT

REF: 16 oz (473ml) 32 oz (946ml) 128 oz (3784ml)

ECI Electro-Gel contains Water, Sodium Chloride, Aragum T-1998 (Gum Acacia, Guar Gum, Xanthan Gum), Potassium Bitartrate (Cream of Tartar), Glycerin, Methylparaben and Propylparaben.

USAGE

For use with non-disposable neurodiagnostic surface electrodes during EEG exams, evoked potential procedures, and brainmapping. For External Use Only.

APPLICATION

Do not use too much gel. The size of the area of gel becomes the effective size of the electrode. This can reduce inter-electrode distances and compromise the exam.

Place a small amount of gel into a clean container. Fill the blunt tip syringe, and inject the gel into each of the recording electrodes. Do not fill the syringe directly from the jar of gel.

If there is no hair at the electrode site, place a sponge disk around the electrode.

CAUTIONS

Use topically on healthy, intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury on the medical condition of the patient.

Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions.

If rash, redness, itching, swelling, or abnormality appears on skin, wash off immediately.

Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites.

Avoid eye contact. May cause mild transient irritation. Wash eyes with appropriate 0.9% saline solution, commercial eye wash solution or water to flush out residual particles. Avoid rubbing eyes.

Patients' tolerance for topical applications to the skin varies widely. Some patients poorly tolerate conductive media and salts. Respond to any complaint that may signal product intolerance.

Long term electrode sites must be checked for irritation and redness at least every 8 hours by removing the cap and/or electrodes and evaluating the skin condition at the electrode sites.

Do not use with current inducing electrodes.

SAFETY AND HANDLING

The gel is essentially non-toxic; however ingestion could result in nausea, vomiting and/or diarrhea. Drink 1 to 2 glasses of water if ingested.

May be disposed of without special handling. Keep containers tightly closed and at room temperature.

Expiration date is found on the bottom of the jar.

Keep out of the reach of children.

Electro-Cap International, Inc.
1011 W. Lexington Rd.
Eaton, OH 45320 USA
937 456-6099

℞ ONLY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Attachment D

Predicate Device Labeling

Ten20 Conductive Paste As taken from: **A0009 Rev 07 ENG**
REF: 10-204 4oz (114 gm) Jar; 10-20-8 8oz (228 gm) Jar; 10-20-4T
4oz Tube (114 gm)
Ten20 Conductive formulation contains: Polyoxyethylene 20 Cetyl Ether, Water, Glycerin, Calcium Carbonate, 1,2 PrOpanedi01, Potassium Chloride, Gefwhite, Sodium Chloride, Polyoxyethylene 20 Sorbitol, Methylparaben, Propylparaben.

—USAGE —
For use with non-disposable neurodiagnostic electrodes during EEG exams, evoked potential procedures, ENG exams, brainmapping, and MSLT procedures.

— APPLICATION —
Do not dispense paste directly onto the electrode or on the head. Place the amount of paste needed on a surface such as a strip of surgical tape.
Do not use too much paste. The size of the area of the paste becomes the effective size of the electrode. This can reduce inter-electrode distances, potential differences measured and compromise the exam. Ten20 Conductive Tube: Press the tube from below to push paste to the top of the tube. Press with the thumb at the top of the tube to dispense the paste.
Ten20 Conductive Jar: Use a tongue blade to remove the paste.

— PASTE WITH GAUZE OR TAPE —
The adhesive quality of Ten20 Conductive is usually sufficient to adhere the electrodes to the skin and provide conductivity for the neurodiagnostic exam.
First, gently abrade the skin with an abrasive product such as Nuprep. Use a bell shaped cup electrode with the hole in the center Apply just enough paste inside of the EEG electrode to very slightly overfill the cup.
Place the electrode onto the electrode site and press with medium pressure. A small amount of paste may come out of the hole. Pressing too hard will cause all of the paste to come out and the electrode will not adhere well.
Use either tape or a postage stamp size piece of gauze to fix the electrode in place.
If the electrode site has hair around it, use a cut up piece of gauze the size of a postage stamp and press onto the electrode. The paste that came out of the hole when it was pressed into place will hold the gauze square. If no paste comes out of the hole, place a small amount of Ten20 Conductive on the gauze and press the gauze onto the electrode using the paste to make it stick.
If the electrode site does not have hair around it, use surgical tape such as 1" Micropore tape to secure the electrodes. Use the same technique as above pressing the electrode into place. Use 3 or 4 cm of tape (1 1/4") to cover the electrode and the lead hub.
This is effective at Fp1, Fp2 and the ground electrode. Do this on any other sites not surrounded by hair if the patient is balding.

— Al and Az —
Attach A l and A2 on the earlobe using the amount of paste as described above. Point the hub of the electrode up and slightly forward.
Allow the lead to come over the top of the ear and then direct it to the back of the head. Use a longer piece of tape than normal so that you cover the hub of the lead, the electrode, then loop the tape to the back of the earlobe.

— CAUTIONS —
Use topically on intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury or the medical condition of the patient.
Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions. If rash, redness, itch, swelling, or abnormality appears on skin, wash off immediately.
Instruct patients to communicate any persistent redness, soreness or swelling at the electrode site. Topical infections can leave permanent scars if left untreated.
Avoid eye contact. If Ten20 Conductive paste is introduced in the eye, rinse with water for 10 to 15 minutes. Avoid rubbing the eyes.
Patients' tolerance for topical applications to the skin varies widely.
Some patients poorly tolerate adhesives, abrasives, conductive media, and salts. Respond to any complaint that may signal product intolerance.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Long term electrode sites must be checked for irritation and redness at least daily by removing the electrode and evaluating the skin condition under the electrode.
Ten20 Conductive Paste contains insoluble materials that may shadow, or interfere with Magnetic Resonance Imaging (MRI) examination.
Prior to an MRI exam, ensure all materials used in the neurodiagnositc examination are cleaned from the electrode sites.
Do not use with current-inducing electrodes.

— SAFETY AND HANDLING —
Ten20 Conductive:
• Excessive exposure may cause fingers to become dry and chapped.
Wash from hands after applying to the patient. If dry hands persist, use gloves when applying the product.
• Is non-toxic if accidentally ingested. • May be disposed of without special handling. Keep containers tightly closed and store at room temperature. Avoid prolonged cold temperature or freezing.

+1-303-366-1804 +1-800-525-2130
Expiration date on bottom. E.C. inquiries: Authorized Representative: Emergo Europe, Molenstraat 15, 2513 BH Information also available at: The Hague, The Netherlands +31 70 345 8570 www.doweaver.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment E
510K summary

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact:	Amy B. Swallows
Phone:	937-456-6099
Fax:	937-456-7323
Summary Date:	June 15, 2011
Trade Name:	Electro-Gel
Common Name:	Electrode Gel
Classification Name:	Media, Electroconductive

Predicate Device(s):

510(k) Number:	K780045
Manufacture:	Electro-Cap International, Inc.
Trade Name:	Electro-Gel

510(k) Number:	K883149
Manufacture:	Weaver and Company
Trade Name:	TEN20 Conductive Paste

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Technological Characteristics

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

4.0 Conclusions

The intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised. The Electro-Gel will perform as well as the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment F

Electro-Gel Risk Analysis

1. PURPOSE

A risk analysis of Electro-Gel produced by Electro-Cap International, Inc. was performed to meet the regulatory requirements standards listed on section 3 in this document.

2. SCOPE

This document applies to the Electro-Gel.

3. REFERENCE DOCUMENTS / APPENDICES

Medical Device Directive 93/42/EEC - Annex II
21 CFR 820: FDA Quality System Regulation
ISO4971:2007 Application of Risk Management to medical devices
5001 - Design Control Procedure
5018 - Risk Analysis Procedure
5019 - Risk Management Plan
5091 - Risk Analysis Summary
Appendix A - Hazard Identification and Evaluation Form
Appendix A - Action Implementation and Effects Form
Appendix B - "Identification of Qualitative and Quantitative Characteristics"
ISO14971:2007, Annex C

4. DEFINITIONS

Risk - The probability of occurrence of harm and the severity of that harm.
Risk Analysis - A systematic use of available information to identify hazards and to estimate the risk.

5. SUMMARY

5.1 A risk analysis of the Electro-Gel was performed on Wednesday, June 08, 2011, at Electro-Cap International, Inc. in Eaton, Ohio. Present and participating in the risk analysis was the Risk Analysis Committee:

W. Nelson Hardin, President
Amy Swallows, Marketing Manager
Janice Pieratt, Quality Control

5.2 The results of the risk analysis are summarized in Appendix A. All identified potential hazards associated with the use of Electro-Gel have been reduced to minor risks. This was accomplished through positive actions that decrease the severity or occurrence of the

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hazard or increase the probability of detection of the potential hazard at receiving inspection or during the manufacturing process.

6. ANALYSIS PROCEDURE

6.1 The risk analysis for the Electro-Gel was accomplished using the Failure Mode Effects Analysis and described in document 5018B Risk Analysis procedure.

6.2 INTENDED USE AND IDENTIFICATION OF QUALITATIVE AND QUANTITATIVE CHARACTERISTICS: (Appendix B)

The risk analysis team shall answer each of the questions shown in Appendix; "Identification of Qualitative and Quantitative Characteristics" ISO14971:2007, Annex C.

6.3 RISK ANALYSIS AND IDENTIFICATION OF HAZARD AND EVALUATION FORM: (Appendix A)

The risk Analysis team identified the hazards and completed the form in Appendix A as instructed in document 5018B Risk Analysis procedure.

6.4 RISK CONTROL ANALYSIS AND IMPLEMENTATION AND EFFECTS: (Appendix A)

The Risk Analysis team analyzed the risk identified in the evaluation form as instructed in document 5018B Risk Analysis procedure.

6.5 ASSESSMENT OF RESIDUAL RISK

No residual risks

6.6 EVALUATION OF ALL IDENTIFIED HAZARDS

All identified hazards are evaluated in Appendix A.

6.7 ADEQUACY OF DEVICE SAFETY

Based on the results of this risk analysis, the risks associated with the intended use and application of Electro-Gel are judged to be acceptable.

7. REVISION HISTORY

Rev	Description of Change	Date
A	Initial	1988
B	Change Preservative from Phenol to Methylparaben & Propylparaben	1991
C	Change Thickening Gum from Tragacanth to Aragum T1998	07/2008

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Appendix B ISO14971:2007 - Annex C
IDENTIFICATION OF QUALITATIVE AND QUANTITATIVE CHARACTERISTICS

1. What is the intended use and how is the medical device to be used?

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

2. Is the device intended to be implanted?

No

3. Is the device intended to be in contact with the patient or other persons?

The Electro-Gel is intended to make direct contact with the skin. Once the data recording is complete, the gel can be simply washed off with soap and water.

4. What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?

By using a syringe and 16 gauge blunted needle, the gel is injected into each of the electrodes mounts that are in contact with the head. The gel is the conductor between the electrode and the scalp.

The chemicals used to manufacture the Electro-Gel are: Water, Sodium Chloride, Aragum T-1998 (Gum Acacia, Guar Gum, Xanthan Gum), Potassium Bitartrate (Cream of Tartar), Glycerine, Methylparaben and Propylparaben.

5. Is energy delivered to or extracted from the patient?

No

6. Are substances delivered to or extracted from the patient?

No

7. Are biological materials processed by the device for subsequent re-use, transfusion, or transplantation?

The Electro-Gel does not process biological materials.

8. Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?

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No

9. Is the medical device intended to be routinely cleaned and disinfected by the user?

No

10. Is the medical device intended to modify the patient environment?

No

11. Are measurements taken?

Electro-Gel does not have a measuring function.

12. Is the device interpretative?

The Electro-Gel is not intended to be interpretive.

13. Is the device intended for use in conjunction with other medical devices, medicines or other medical technologies?

Yes. The Gel is used in concert with EEG/EP devices. Patient isolation and other such matters are addressed by the equipment manufacturers.

14. Are there unwanted outputs of energy or substances?

No

15. Is the device susceptible to environmental influences?

The Electro-Gel must be store in room temperature and must be kept in the jar with the lid tightly closed.

16. Does the medical device influence the environment?

No

17. Are there essential consumables or accessories associated with the medical device?

Electro-Gel is a consumable product.

18. Is maintenance or calibration necessary?

No

19. Does the device contain software?

No

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20. Does the device have a restricted shelf life?

Yes, the Electro-Gel has a shelf-life of 2 years.

21. Possible delayed or long-term use effects?

There are no significant effects associated with long-term use however long term electrode sites must be checked for irritation and redness at least every 8 hours. Electro-Gel has passed sensitivity and irritability testing.

22. To what mechanical forces will the medical device be subjected?

Electro-Gel is injected into an electrode and is kept within the electrode cup. The electrodes rest on the subject's skin.

23. What determines the lifetime of the medical device?

Historical usage over 23 years indicates Electro-Gel's useful life to be greater than 2 years without a decrease in performance or safety.

24. Is the medical device intended for single use?

Electro-Gel is a consumable product and is for one time use only.

25. Is safe decommissioning or disposal of the medical device necessary?

No

26. Does installation or use of the medical device require special training or special skills?

The Electro-Gel is intended to be used by trained technicians.

27. How will information for safe use be provided?

The user will receive a copy of a Direction For Use And Cautionary Statement with every jar of Electro-Gel, until it is printed on the jar. This gives clear instruction and cautions on the use of the gel.

28. Will new manufacturing processes need to be established or introduced?

No, the gel will be produced according to the approved manufacturing procedures used for 23 years.

29. Is successful application of the medical device critically dependent on human factors such as the user interface?

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The application of the device is dependent on the technician who is applying the gel. If too much gel is used, the size of the area of gel becomes the effective size of the electrode and can reduce inter-electrode distances and may compromise the exam.

29.1 Can the user interface design features contribute to use error?

If too much gel is used, the user runs the risk of the gel coming out of the electrode cup, therefore creating bridging between electrodes. The bridging does not affect the subject, but the actual test may be in jeopardy. There is no risk to the subject.

29.2 Is the medical device used in environment where distractions can cause use error?

No

29.3 Does the medical device have connecting parts or accessories?

No

29.4 Does the medical device have a control interface?

No

29.5 Does the medical device display information?

No

29.6 Is the medical device controlled by menu?

No

29.7 Will the medical device be used by persons with special needs?

No

29.8 Can the user interface be used to initiate user actions?

No

30. Does the medical device use an alarm system?

No

31. In what way(s) might the medical device be deliberately misused?

Electro-Gel is safe to use. Although an allergic reaction is very rare, the Electro-Gel may cause skin irritation to subjects with a history of sensitive skin.

32. Does the medical device hold data critical to patient care?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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No

33. Is the medical device intended to be mobile or portable?

Portable

34. Does the use of the medical device depend on essential performance?

No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

APPENDIX A

RISK ANALYSIS FOR ELECTRO-GEL

(REF ISO14971:2007 TABLE E)

Potential Hazard	Failure Mode	Failure Cause	SI	O1	D1	RPN1	Classification	Action
Skin Irritation	Skin irritation from the conducting gel	Allergic Reaction	3	2	10	60	Minor	None Required
Inconsistent Gel Formulation	Operator not following mfg. procedure	Wrong formula used	3	2	5	60	Minor	None Required
Mold on Gel	Preservative not added to formulation	Gel not usable	4	2	5	60	Moderate	None Required
Gel to Viscous	Gel does not remain in contact with electrode	Gel not stored properly	2	1	5	60	Minor	None Required
Too Much Gel Inserted Into Electrode	Electrodes may bridge together	Technician error	4	2	10	60	Moderate	None Required

S1 = Severity level prior to implementation of means for risk reductions:	10(high)...	10(high)...
S2 = Severity level after implementation of means for risk reductions:	10(high)...	10(high)...
O1 = Probability of occurrence prior to implementation for means for risk factor:	10(high)...	10(high)...
O2 = Probability of occurrence after implementation for means for risk factor:	10(high)...	10(high)...
D1 = Probability of detectability (during raw material or manufacturing process inspections) prior to implementation for means of risk reduction:	10(high)...	10(high)...
D1 = Probability of detectability (during raw material or manufacturing process inspections) after implementation for means of risk reduction:	10(high)...	10(high)...
RPN1 = Risk Priority Number prior to implementation of means risk reduction:	Minor: RPN <61	
RPN2 = Risk Priority Number after implementation of means risk reduction:	Minor: RPN <61	

RISK ANALYSIS SUMMARY

ACTION IMPLEMENTATION AND EFFECTS FORM

Action To Be Taken	S2	O2	D2	RPN2	Classification
Mold will grow on the gel in 2 weeks if preservatives are not added to the formulation. If there is no mold on the gel without the preservative used on the subject, there is no harm to the subject	3	1	5	54	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510K summary

DUPLICATE

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact:	Amy Swallows
Phone:	937-456-6099
Fax:	937-456-7323
Summary Date:	June 15, 2011 (Revised November 30, 2011)
Trade Name:	Electro-Gel
Common Name:	Electrode Gel
Classification Name:	Media, Electroconductive
Regulation Number:	21 CFR 882.1275
Product Code:	GYB

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Electro-Gel is an off white color, water-miscible conductive gel consisting of Sodium Chloride as the conductor combined with thickening agents, emulsifiers, humectants and preservatives all in an aqueous solvent. The pH range is 3 - 7 pH. It is available in the following jar sizes: 16 ounce, 32 ounce and 128 ounce.

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Predicate Comparison

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

(Please refer to the comparison tables on the following four pages).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.	K111717	K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 4.0. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.	K111717	K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

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Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, conductivity and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name John Grimes

Subject: 510(k) Number K111717/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21		✓	

Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code
21 CFR 882.1275	II	GYB

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) NNDB (Branch Code) 1/5/2012 (Date)

Final Review: (Division Director) 1/5/12 (Date)

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Grimes, John

From: Grimes, John
Sent: Thursday, January 05, 2012 3:36 PM
To: 'Amy Swallows'
Subject: Notification of Minor Changes to 510(k) Summary Prior to Publication

Dear Ms. Swallows,

This letter is to inform you that the following minor changes have been made to your 510(k) Summary, which will be made publicly available on FDA's website as a convenience for your firm:

- The amounts of the ingredients, listed after the ingredient name, used in the gel were removed (e.g.: "Water 40 gallons" becomes: "Water", "Potassium bitartrate 2.65 lbs." becomes "Potassium bitartrate", etc.). The actual list of ingredients remain.
- The "Confidential" footer at the bottom of the pages was removed
- Incorrect references to number of pages, table numbers, etc. were removed and/or corrected.

Please be aware that the 510(k) Summary will be placed on-line as a convenience to your firm. If you do not wish to have the 510(k) Summary publicly available on FDA's web site, you will need to submit a 510(k) Statement, which indicates that you agree to provide any requestor such information within a specified timely manner.

Please reply to this e-mail confirming that this is acceptable, or, if unacceptable, please provide a proper 510(k) Statement.

Thank you,

==========

John Grimes, Ph.D.
Biomedical Engineer / Lead Reviewer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic Neurological and ENT Devices
Neurodiagnostic and Neurotherapeutic Devices Branch
[FDA / CDRH / ODE / DONED / NNDB]

10903 New Hampshire Avenue
WO66 Room 2629B
Silver Spring, MD 20993
john.grimes@fda.hhs.gov
office: (301)796-2349
fax: (301)347-8126
fax: (301)347-8127

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

7

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Grimes, John

From: Amy Swallows [aswallows@electro-cap.com]
Sent: Thursday, January 05, 2012 3:41 PM
To: Grimes, John
Subject: RE: Notification of Minor Changes to 510(k) Summary Prior to Publication

Dear Mr. Grimes,

Thank you for your message. With the changes made as outlined in your email below, it is acceptable to us that the 510(k) Summary be placed on-line on FDA's website. If you need any additional information, please do not hesitate to contact us.

Best regards,
Amy Swallows

Electro-Cap International, Inc.
Amy Swallows
Director of Marketing
Eaton, OH
TEL: 800 527-2193
937 456-6099
FAX:937 456-7323
Email: eci@electro-cap.com
Or aswallows@electro-cap.com
www.electro-cap.com

From: Grimes, John [mailto:John.Grimes@fda.hhs.gov]
Sent: Thursday, January 05, 2012 3:36 PM
To: 'Amy Swallows'
Subject: Notification of Minor Changes to 510(k) Summary Prior to Publication

Dear Ms. Swallows,

This letter is to inform you that the following minor changes have been made to your 510(k) Summary, which will be made publicly available on FDA's website as a convenience for your firm:

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- The "Confidential" footer at the bottom of the pages was removed
- Incorrect references to number of pages, table numbers, etc. were removed and/or corrected.

Please be aware that the 510(k) Summary will be placed on-line as a convenience to your firm. If you do not wish to have the 510(k) Summary publicly available on FDA's web site, you will need to submit a 510(k) Statement, which indicates that you agree to provide any requestor such information within a specified timely manner.

Please reply to this e-mail confirming that this is acceptable, or, if unacceptable, please provide a proper 510(k) Statement.

Thank you,

==========
John Grimes, Ph.D.
Biomedical Engineer / Lead Reviewer

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic Neurological and ENT Devices
Neurodiagnostic and Neurotherapeutic Devices Branch
[FDA / CDRH / ODE / DONED / NNDB]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Center for Devices & Radiological Health
Division of Ophthalmic, Neurological, and Ear Nose and Throat Devices

Premarket Notification [510(k)] Review - Traditional
K111717/S002

Date: January 5, 2012
To: FILE
From: John Grimes, Ph.D., Biomedical Engineer and Lead Reviewer (DONED/NNDB) John Grimes
Through: Quynh Hoang MS, Branch chief (DONED/NNDB) QHoang 1/5/2012
Malvina Eydelman MD (Division Director, DONED) _____

Subject: Review of **Electro-Cap International's** *(sponsor)* Premarket Notification for their *modified* device, the **Electro-Gel** *(device)*.

Contact: Amy B. Swallows
Director of Marketing
1011 West Lexington Rd
Eaton, OH 45320
Ph: (937) 456-6099 Fax: (937) 456-7323
Email: aswallows@electro-cap.com

Summary/Recommendation:

I recommend that this device be found SUBSTANTIALLY EQUIVALENT.

The sponsor, following an interactive response to raise the pH range from 4 – 6 to 4.5 – 6, has satisfied all outstanding deficiencies.

This is supplement 2. The review for the original submission was done by Sara Aguel, Biomedical Engineer (DONED/NNDB). Her original comments are denoted within this review as (Original). Comments made in previous submission are denoted within this review as (S001).

The Electro-Gel is a water-soluble, electro-conductive gel intended for use with Electro-Cap International's Electro-Cap device and other non-disposable, recording, external electrodes.

I. Purpose

This is a supplement to previous 510(k) submission K111717 to respond to an additional information request. The 510(k) holder would like to introduce their modified Electro-Gel into interstate commerce.

II. Regulatory History

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(Presented by Reviewer of original submission, Sara Aguel, Biomedical Engineer (DONED/NNDB)

Office of Compliance (OC) inspected Electrode-Cap International earlier this year. Among many things, they identified concerns with two formula changes the gel has undergone since last clearance in K780045. Specifically (excerpt from e-mail exchange with OC; see attached for full report):

> According to Mr. Hardin, Electro-Gel has undergone two formula changes. Validation was not performed on either change and the firm does not have design control procedures.
>
> Approximately 10-15 years ago, the firm switched from using Phenol Acid in the gel to using Methylparaben and Propylparaben. Mr. Hardin stated that Dr. Ajaz Hussain from the University of Cincinnati did research through literature to determine this change. Dr. Hussain's research is not documented. Mr. Hardin stated that no testing was done to confirm that the gel was still functioning at the same capacity as the previous formula.
>
> A second change was made to the gel approximately three years ago. The firm was originally using Tragacanth, Powder as a component of the gel. The firm discontinued the use of Tragacanth powder and started using TIC Aragum T-1998. TIC Aragum T-1998 is a mixture of Arabic Gum, Guar Gum, and Xanthan Gum manufactured by TIC Gums, 4609 Richlynn Drive, Belcamp, MD 21017. Mr. Hardin stated that the firm provided a jar of Electro-Gel to TIC. According to Mr. Hardin, TIC stated that Aragum T-1998 is the same viscosity as the Tragacanth powder. Mr. Hardin did not have any documentation of testing.
>
> .....
>
> In addition to the components being changed in the formula, the specifications have not been identified. Mr. Hardin stated that the firm does not have any specifications for the viscosity of the gel. The firm measures the viscosity of each batch of gel being manufactured, but there are no specifications to check the results of testing the viscosity. Mr. Hardin stated that he is unsure of the specifications for the conductivity of the gel. Mr.. Hardin stated that the employee who manufactures the gel would not know the specifications for the gel conductivity. A former employee tested the conductivity of the gel until March 2011. Mr. Hardin stated that the firm stopped testing gel conductivity after the employee left the firm. Mr. Hardin stated that there was no variation in the gel conductivity for two years prior to ending the conductivity testing. Mr. Hardin stated that the conductivity specifications were on a quality improvement procedure. Mr. Hardin stated that the results of conductivity testing and the conductivity testing procedure are on the former employees computer. Mr. Hardin was not able to furnish this documentation on 04/20/2011.

OC asked ODE whether the above gel changes warranted a new 510(k). Quynh Hoang and I both responded that yes, a new 510(k) was needed given the changes sine the original clearance could significantly affect the safety and effectiveness of the device. This 510(k) is the sponsor's response to this determination and only their second 510(k) submission.

A search on FDA's public 510(k) database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm) shows that 57 510(k)s have been cleared as "electroconductive media" (under GYB, 882.1275) since 1977. The most recent was cleared in 2004.

A search on FDA's public adverse event/MAUDE database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm) shows that 68 adverse events have been reported under "GYB," a vast majority of them for the Weaver Company's TEN20 conductive paste and Nuprep gel.

III. Device Description

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) device description

(b)(4) device description

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Electro-Gel is intended for use in clinical and research EEG/EP **recordings** from humans. It is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Reviewer Comment (Original): No comment at this time. See "Predicate Device" section below.

V. Predicate Devices

The sponsor asserts substantial equivalence to their own Electro-Cap VII System, cleared in **K780045**, and the Weaver TEN20 Conductive Paste (**K883149**).

Though the sponsor does not reference them, other relevant predicates to this review include more recent electroconductive gel clearances such as the Mavidon Medical Electrode Jelly (**K003924**) and Compumedics Quik Gel (**K033052**).

For reference, the cleared Indications for these predicates are outlined below. Those in bold represent the sponsor's identified predicates.

K780045	**Electro-Cap Inc Electro-Cap VII System**	*Prior to IFU Statement, but review memo states:* "An array of prepositioned electrodes arranged in a "hat" to facilitate multi-lead EEG recording. Consists of several parts that are replaceable."
K883149	**Weaver Ten20 Conductive Paste**	*Prior to IFU Statement; Review memo makes no statement of intended use.*
K003924	Mavidon Medical Electrode Jelly	"The Mavidon Medical Electrode Jelly is recommended for use with silver, gold, or tin electrodes in EEG, ECG, EMG, TENS and Muscle Stimulation procedures.
K033052	Compumedics Quik Gel	"The Quik gel is intended to enhance electrical conductivity by facilitating transmission of the electrophysiological signals from the patient to the equipment to reduce impedance at the electrode-to-skin interface. It also helps the Quik cap electrodes adhere to the patient."

Reviewer Comment (Original): The proposed indication is nearly identical to that cleared for the most recent predicate cited above, K033052. The most major differences are the specific references to use in "EEG/EP *recordings*" and "with external electrodes." I find both of these additions adequate as they are consistent with how the sponsor describes the device in other parts of the 510(k) and because they serve to clarify the device's limits of use.

VI. Predicate Comparison

The sponsor submitted a predicate comparison table in Section 3, page 6.

Reviewer Comment (Original): Please see Table 1 below for details of my comparison of the subject device with the above cited predicates. Per my review of the predicate 510(k)s and the differences I note in the table below, my comments are as follows:

- **The sponsor's own previous 510(k), K780045, includes clearance of the Electro-Cap VII**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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System (which itself consisted of an electrode cap, electrode board harness, body harness, "quick-insert" electrode, disposable sponge disks and needle/syringe "kit"), **"Ear Electrode" and "Electrode Gel." The review memo for this 510(k) is sparse, and only references questions related to the cleaning instructions in *electrode cap's* labeling. I could find little to no detail or review related to the electrode gel.**

- **Reviews of electro-conductive media seem to have become more comprehensive after Electro-Cap's 1978 510(k). For example, in *all* of the 510(k)s I reviewed (from 1988, 2000 and 2003), the sponsor provided (or the reviewer requested) the concentrations of ingredients in the gel (or a manufacturing procedure with specific amounts) and biocompatibility testing. Additionally, two of the three predicates described the pH of the gel. As this precedent is the more recent and more prolific in the regulatory record than K780045, I recommend the sponsor provide this information prior to clearance. It is also important as the composition of the subject Electro-Gel is different from the predicates. See also the Device Description section above and Biocompatibility section below.**

- **FDA has recently released DRAFT guidance for Electroconductive Media** (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199256.htm). **This guidance recommends** (in addition to a "written description of all ingredients and concentrations," "identification of the pH in the gel formulation" and biocompatibility testing, as referenced above) **that sponsors "evaluate and document the electroconductive medium's...electrical performance and stability to assure that the device performs as intended." Specifically:**

  - The electroconductive medium should be effective in conducting electrical current across the electrode-skin interface. We recommend that you perform impedance testing to assure that the electroconductive medium has conductive properties that are appropriate for the device's intended use.

  - Electroconductive media should be stable and resist physical and chemical breakdown as a result of conducting electrical current and extended periods of storage over a range of environmental conditions. We recommend that you perform testing to establish, for labeling purposes, the device's shelf life and storage conditions.

While I find the above recommendations scientifically valid, because this guidance is still in draft form (i.e., out for public comment, not yet for implementation) and because it concurrently recommends that electro-conductive media be exempt from 510(k) requirements, I must look to the regulatory precedent for guidance about what is appropriate to ask for in this 510(k).

In my limited review of the 57 devices cleared under the 'electroconductive media" regulation, I found a range of requirements for conductive testing. For example:

- ***K883149*: Sponsor provided a summary of results from conductive testing done in an independent lab (page 10 of response to reviewer questions).**

- ***K003924*: Sponsor provided detailed list of product specifications and** "Performance Standards Certification" **stating the device "meets all its requirements including pH, viscosity, conductivity and ingredient mixture."** ***See attached for a copy of this statement.***

- ***K033052*: No documentation of conductive performance or characteristics, and no request for such data from FDA.**

In this 510(k), the sponsor states "The conducting agent of the gel is Sodium Chloride with a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ratio of 30 pounds dissolved in 40 gallons of water has been used for more than 30 years" and "During this period there has never been a customer complaint concerning the conductivity of the gel" **(Original submission, page 8 of 34). Since there is no strong regulatory precedent and because the conductive material is similar to that in at least two other non-Electro-Cap cleared 510(k)s, I do not think it necessary to require the sponsor to provide a summary of results from conductive testing. However, I do recommend the sponsor provide specifications and a signed certification that the gel has been tested and meets its design requirements, "including pH, viscosity, conductivity and ingredient mixture." My rationale for this request is as follows:**

- **A lack of "customer complaint concerning the conductivity of the gel" is an inadequate measure of device performance.**
- **OC has noted a lack of conductivity specification and testing in their recent inspection of the sponsor's facilities (see Regulatory History section above an attached e-mail).**
- **There is precedent for this type of documentation for device performance in at least one (relatively) recent predicate 510(k) (K003924).**

- **I have not yet found testing details in predicate 510(k)s related to stability testing, but all three of the predicates referenced above do provide a shelf life (i.e., expiration) in the device labeling. The current sponsor, Electro-Cap, also provides an expiration date (2 years). In order to provide an expiration date, appropriate design controls would include an assessment of the gel's stability up until this date. While I expect this information to be in the sponsor's device master records** (21 CFR 820.3(j)), **because of the lack of regulatory precedent, I will not ask for the sponsor to provide it in the 510(k).**

For my specific recommended deficiencies, see the Deficiencies section below.

Table 1: Comparison of Electro-Gel to Relevant Predicates (**Updated** to reflect S001)

	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
Type of Electrodes Used With	Recording only	Recording	Recording and TENS stimulation electrodes	Recording	Recording only; not for use on "current inducing electrodes"
Ingredients	"commercial lubricating jelly (eg. Lubrafax, K-Y Jelly) with sodium chloride added (approximately one ounce of sodium chloride to 16 ounces of lubricating jelly) to aid in conductivity."	Water Potassium Chloride (conductive) Sodium Chloride (conductive, ionic) "Brij 58" (surfactant) Atlas G-1726 (non-ionic surfactant) Glycerin	Water Cullinix 999 Mixing Salt (sodium chloride) Potassium Bitarttrat Glycerine 99% Phenol Cellosize QP –	Distilled Water Potassium Chloride Calcium Chloride Baking Soda ($NaHCO_3$) Gylcerin Soluble Starch ($C_6H_{10}O_5$) Micananzole	Water Sodium Chloride (conductive) Aragum T-1998 Powder (viscosity) Potassium Bitartrate (Cream of Tartar) ("improve electrode contact") Glycerin

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
		("incorporation factor") Calcium carbonate ("calcium compound") 1,2-Propanediol (propylene glycol) (emulsifier) Gelwhite H (Bentonite) (suspension agent) Dowicil 200 (bacteriostatic agent)	100M-H Pigment	($C_{18}H_{14}C_{14}N_{20}$ HNO_3) Clotrimazole anti-fungal	(humectant, preservative, viscosity) Methylparaben (preservative) Propylparaben (preservative)
Ingredient concentrations provided?	No	Yes	Yes	Step-by-step procedure followed to formulate gel – including amounts, timing, temps – provided (Att E)	Yes
pH of gel formation	*unknown*	6.00 to 6.50	7 +/- 0.5	*unknown*	4.5 – 6
Duration of Use	*unclear*		1 hour	*unclear*	Maximum of 8 hours
Biocomp-atibility Testing provided?	No	**Yes, of final product** – skin irritation. Also provided chemical and toxicity information on individual ingredients (Brij 58, Atlas G 1726, Dowicil 200, Gelwhite H)	**Yes, of final product** –skin irritation, dermal sensitization, cytotoxicity	**Yes, of final product** - irritation, sensitization, dermal sensitization, cytotoxicity,	**Yes.** Agar Diffusion Test ISO 10993-5,-12 Primary Skin Irritation Test-ISO Direct Contact ISO 10993-10,-12 and Buehler Sensitidation Test ISO 10993-10,-12
Impedance Testing?	None provided	**Yes** – testing done by independent lab; gel impedance is between 1-3 kOhms	No specific protocols provided, but Specifications provided and a	None provided	Design specifications and certification statement that the gel has been tested

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
			"Performance Standards Certification" that states device "meets all its requirements including pH, viscosity, conductivity and ingredient mixture"		and meets the specifications 0.5 kΩ or less
Shelf life	*unknown*	"Product lot # and expiration date will be displayed on each container"	6 months	"The expiration date is on the bottom of each bottle"	1 year, "if stored properly, i.e. kept with containers tightly closed and at room temperature."
Storage conditions	*unknown*	"Keep lid closed when not in use. Room temperature."	*unknown*	*unknown*	Room temperature; original container; lid tightly closed

VII. Performance Testing

a. Bench and Clinical

Related to performance testing, the sponsor provided:

- A viscosity check procedure
- A pH check procedure
- An impedance check procedure
- A quality assurance procedure

The sponsor also included a certification that the product meets the design specification for the product.

Reviewer Comment (S001):
The sponsor provided the requested design specifications and certification statement that the gel meets the specifications.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

b. Electrical and EMC Safety

Not applicable. Device does not include any electronic components.

c. Software

Not applicable. Software is not a part of this device or 510(k).

VIII. Sterilization

Not applicable. Device not provided sterile (Original submission, page 7).

IX. Biocompatibility

The sponsor provided biocompatibility testing results conducted by Toxikon, in accordance with the recommendations in FDA's Blue Book memorandum G95-1 and ISO 10933-1, as requested by FDA. These tests include:

- Agar Diffusion Test, ISO 10993-5,-12
- Primary Skin Irritation Test-ISO, Direct Contact, ISO 10993-10
- Buehler Sensitization Test, ISO 10993-10

CURRENT REVIEWER COMMENT:
A biocompatibility consult was performed by Shelley Buchen in S001. Subsequent discussions about biocompatibility concerns were performed for this review. These e-mails are attached at the end of the review.

Please also see Section XIII, Response to Deficiencies, below.

X. Labeling

The sponsor provided their proposed labeling in Attachment C of the submission.

The sponsor lists the following important items in their labeling:

- List of ingredients
- Storage instructions
- Storage instructions: "Keep containers tightly closed and at room temperature."
- Expiration: "Expiration data is found on the bottom of the jar"
- "For External Use Only"
- "Use topically on healthy, intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury on the medical condition of the patient."
- "Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions."
- "If rash, redness, itching, swelling, or abnormality appears on skin, wash off immediately. Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites."
- "Avoid eye contact."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

- "Do not use with current inducing electrodes."
- "Keep out of the reach of children."

Reviewer Comment (Original): I recommend the labeling add the following:
- **Maximum duration of use**
- **How to remove the gel from the electrode and skin following use**
- **Caution that gel should not be reused.**
- **IFU ("Usage") statement modified to be identical to that stated on the IFU statement.**

For my specific recommended deficiency, see the Deficiencies section below.

Reviewer Comment (S001):
The sponsor provided updated labeling, as requested.

XI. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

   The new indication for use is not materially different from predicate devices. Only word choice exists. The new IFU is also more limiting in that it specifies "recording" and "external electrode" and "scalp" contact.

2. Explain why there is or is not a new effect or safety or effectiveness issue:

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The materials used are similar to those used in predicate devices. Further, since biocompatibility tests and consults show no safety or effectiveness problems and the IFU further limits the device's use to external electrodes for recording, no new safety/effectiveness concerns are raised.

3. Describe the new technological characteristics:

   N/A

4. Explain how new characteristics could or could not affect safety or effectiveness:

   N/A

5. Explain how descriptive characteristics are not precise enough:

   N/A

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XII. Administrative Requirements

	Yes	No
Indications for Use page (**Prescription**)	X	
Truthful and Accuracy Statement	X	
510(k) Summary or 510(k) Statement	X	
Standards Form		X
ClinicalTrials.gov Certification form		X

XIII. Response to Deficiencies

The original Deficiency is presented in *italics*
The sponsor's response is presented in underlined text
Reviewer comments are presented in **bold**

Biocompatibility

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1. *You state that the pH range of the Electro-Gel is 3-7. This range is believed to be too large. Further, a pH of 3 may be irritating to some sensitive individuals. Although your device was found non-irritating to the rabbit in the Irritation Test, the exposure time in that test was only 4 hours versus a maximum exposure time of 8 hours for your device in the human. The specification for the pH of a device should be based on the actual values obtained for the lots used in biocompatibility testing, and a narrow range would help provide assurance that the manufacturing process is well-controlled. Therefore, unless you can provide a scientific justification for the pH specified, please provide us with a new pH specification with a smaller range and a value higher than 3 at the lower end. Additionally, please revise your labelling accordingly.*

   We are revising the acceptable ph range of Electro-gel to 4-6. We are enclosing the revised 510(k) Summary, the manufacturing procedures, and the Electro-Gel Certification reflecting this change.

After consulting with Shelley Buchen, concerns were still raised about the pH level being too acidic. Ms. Buchen stated she would have no further concerns with the pH range if the sponsor agreed to change the pH range to 4.5 – 6. With regards to the duration of contact during testing only lasting 4 hours and the indication for use statement indicating a maximum of 8 hour usage, Ms. Buchen had no concerns.
The sponsor agreed, through interactive review via e-mail, to change the pH range to 4.5 – 6 and submitted an updated 510(k) Summary, Manufacturing Procedure, and Certificate reflecting this. E-mails with Ms. Buchen and the sponsor are attached at the end of this review.

Device Description

2. *In response to prior Deficiency #1, you provide the amounts (by weight) for six of the seven gel solutes. However, you do not specify the concentration of glycerine directly. Please clarify that the amount of glycerine used is 2 gallons, as indicated by your provided manufacturing procedure.*

   We have revised our Device Description in the 510(k) Summary to include the glycerine that was inadvertently omitted from our previous response. A copy is attached

   This is acceptable.

3. *In response to prior Deficiency #3, you state that the conductivity of the gel is 0.5 kΩ or less. However, kΩ is the unit of measurement for resistance and impedance (resistance to an alternating current). The unit of measurement for conductance is siemens (S). Please clarify that the impedance of the gel is 0.5 kΩ.*

   We have revised our 510(k) Summary and our manufacturing procedures to show that the impedance of Electro-Gel is .5kΩ. Copies are attached. Our attached Electro-Gel certification also reflects this change.

   This is acceptable.

Administrative

4. *In response to prior Deficiency #5(c), you provide an updated 510(k) Summary (via Addition 1, received 23 November 2011, and Addition 2, received 1 December 2011). You include the pH*

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range of the gel and the available container sizes. However, you do not include the specific concentrations of the solutes used or the maximum duration of use. Please revise your 510(k) Summary to include the solute concentrations and the maximum duration of use. Please note that concentration is typically provided as a molarity or molality.

We have attached a copy of our revised 510(k) summary, which now includes the specific amounts of solutes used in manufacturing Electro-Gel. Please note that we have retained our original units of measurement. Also, our labeling has been revised to reflect the change in shelf life of Electro-Gel from 2 years to 1 year. We have also specified continual use for no longer than 8 hours.

This is acceptable.

XIV. Consults

I informally consulted Shelley Buchen with regards to biocompatibility. She recommended interacting with the sponsor to raise the pH range from 4 – 6 to 4.5 – 6. She had no other concerns. E-mails of this exchange are attached.

XV. Contact History

During the review of S002, the sponsor was contacted via e-mail on 30 December 2011 to request a pH range change to 4.5 – 6. The sponsor replied later on the same day agreeing and submitting updated

Additional contact with the sponsor was to respond to questions via e-mail concerning whether the needed to submit additions to the DMC and to status requests on their file.

XVI. Recommendation

I recommend that this device be found SUBSTANTIALLY EQUIVALENT.

John Grimes

John Grimes, Ph.D., Biomedical Engineer and Lead Reviewer **05 Jan 2012**
Neurodiagnostic and Neurotherapeutic Branch
Division of Ophthalmic, Neurological and ENT Devices

Attachments:

- Interactive communication with sponsor (e-mails).
- Sponsor's updated 510(k) Summary, manufacturing procedure, and certification
- Informal biocompatibility consults with Shelley Buchen (e-mails).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Documents:

- Interactive Review with Sponsor (2 e-mails)
- Sponsor's Updated 510(k) Summary
- Sponsor's Updated Manufacturing Process
- Sponsor's Updated Certification that product meets specifications

Num. Pages:

- 2
- 7
- 3
- 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Grimes, John

From: Grimes, John
Sent: Friday, December 30, 2011 1:39 PM
To: 'Amy Swallows'
Subject: Interactive Review: K111717/S002

Dear Ms. Swallows,

With regards to your current 510(k) Submission for Electro-Gel (K111717/S002), we still have concerns about the pH ranges. We would like to see a pH range of 4.5 - 6 for the product (less acidic). Please send an e-mail stating whether you agree to this change or not, along with an updated 510(k) Summary and other documents that reflect this pH change in PDF format.

Thank you and Happy New Year,

==========

John Grimes, Ph.D.
Biomedical Engineer / Lead Reviewer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic Neurological and ENT Devices
Neurodiagnostic and Neurotherapeutic Devices Branch
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fax: (301)347-8127

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Grimes, John

From: Amy Swallows [aswallows@electro-cap.com]
Sent: Friday, December 30, 2011 2:52 PM
To: Grimes, John
Subject: RE: Interactive Review: K111717/S002
Attachments: Electro-Gel 510(k) 123011.pdf

Dear Mr. Grimes,

Thank you for your message. We are in agreement with changing the acceptable pH range of Electro-Gel to 4.5 – 6. The attached file includes our 510(k) Summary, our manufacturing procedures for the product, and our Electro-Cap Certificate reflecting this change.

Please let us know if you need anything further.

Happy New Year to you, too!

Best regards,
Amy

From: Grimes, John [mailto:John.Grimes@fda.hhs.gov]
Sent: Friday, December 30, 2011 1:39 PM
To: 'Amy Swallows'
Subject: Interactive Review: K111717/S002

Dear Ms. Swallows,

With regards to your current 510(k) Submission for Electro-Gel (K111717/S002), we still have concerns about the pH ranges. We would like to see a pH range of 4.5 - 6 for the product (less acidic). Please send an e-mail stating whether you agree to this change or not, along with an updated 510(k) Summary and other documents that reflect this pH change in PDF format.

Thank you and Happy New Year,

==========

John Grimes, Ph.D.
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510K summary

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact: Phone: Fax:	Amy Swallows 937-456-6099 937-456-7323
Summary Date:	June 15, 2011 (Revised December 30, 2011)
Trade Name:	Electro-Gel
Common Name:	Electrode Gel
Classification Name:	Media, Electroconductive
Regulation Number:	21 CFR 882.1275
Product Code:	GYB

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) device description

[redacted]

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Predicate Comparison

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

(Please refer to the comparison tables on the following four pages).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.	K111717	K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 4.0. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.	K111717	K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

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4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, impedance and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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MANUFACTURING PROCEDURE
ELECTRO-GEL

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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eci

ELECTRO-CAP INTERNATIONAL, INC
1011 W. Lexington Rd., Eaton, OH, 45320, USA
TEL: 937 456-6099 FAX: 937 456-7323 email: eci@electro-cap.co

ELECTRO-GEL CERTIFICATION

The current (after July 2008) formula of Electro-Gel has been, and is, tested for viscosity, pH, and impedance. Electro-Gel meets all of the requirements listed below. These requirements are in accordance with the design specifications for this product.

	Acceptable Range
Viscosity:	575 to 615 cp
Impedance:	0.5 kΩ or less
pH:	4.5 - 6 pH
Ingredients Mixture:	Manufacturing Procedure Attached

Amy Swallows 12-30-11
Amy Swallows
Electro-Cap International, Inc.

rev. 12/30/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Documents: Informal Biocompatibility Consult with Shelley Buchen (via e-mail)

Num. Pages: 9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Grimes, John

From: Grimes, John
Sent: Wednesday, December 21, 2011 1:31 PM
To: Buchen, Shelley
Subject: Biocompatibility Consult: K111717/S002

Shelley,

I just received Supplement 2 for the file you reviewed for me last week (fastest turn around EVER... they got it on the 16th and I got it returned today).

Briefly,

- They revised the pH range to 4 - 6, but I don't know if that's too low or not.
- They did not change the labeling to be 4 hour or less (as we had asked)
- They did not provide any new testing-- neither an increased time to 8 hours, nor provided the pH of the gel actually tested (as we had asked).

The 90th day is 5 Jan 2012. Is there any way you can provide a consult before this date? I am leaving today, but I will be back at work the 29th and 30th.

Please let me know.

Thanks!
--Nicky

==========

John Grimes, Ph.D.
Biomedical Engineer / Lead Reviewer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic Neurological and ENT Devices
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Grimes, John

From: Buchen, Shelley
Sent: Wednesday, December 21, 2011 3:04 PM
To: Grimes, John
Subject: RE: Biocompatibility Consult: K111717/S002

Nicky,

Just to clarify. When I asked the sponsor to change the labeling, I meant the labeling for pH only, not the exposure time. The irritation test performed was in fact performed in accordance with the ISO standard on irritation testing, which specifies a minimum exposure time of 4 hours and most people do expose the test material to the rabbit for 4 hours in the test. I commented on this exposure time because I was concerned about the low pH. It is no longer a concern if the sponsor were to increase the pH value at the lower end. Further, the sensitization test they performed included exposure of the material to guinea pigs for extended periods of time and there was no signs of irritation. I would accept a range of 4.5 to 6 from a biocompatibility standpoint. In the interest of time, you may want to interact with the sponsor and see if they are willing to change the pH range from 3-7 to 4.5-6, which is generally considered the normal pH of human skin. If they do, I have no further concerns.

Shelley

From: Grimes, John
Sent: Wednesday, December 21, 2011 10:31 AM
To: Buchen, Shelley
Subject: Biocompatibility Consult: K111717/S002

Shelley,

Just received Supplement 2 for the file you reviewed for me last week (fastest turn around EVER... they got it on the 16th and I got it returned today).

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Please let me know.

Thanks!
--Nicky

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Grimes, John

From: Grimes, John
Sent: Wednesday, December 21, 2011 3:19 PM
To: Buchen, Shelley
Subject: RE: Biocompatibility Consult: K111717/S002

Shelley.

Sounds good. I will scan and e-mail you their S2 as soon as I get done with this other 510k review that's due today.

Thank you!
--Nicky

From: Buchen, Shelley
Sent: Wednesday, December 21, 2011 3:04 PM
To: Grimes, John
Subject: RE: Biocompatibility Consult: K111717/S002

Nicky,

Just to clarify. When I asked the sponsor to change the labeling, I meant the labeling for pH only, not the exposure time. The irritation test performed was in fact performed in accordance with the ISO standard on irritation testing, which specifies a minimum exposure time of 4 hours and most people do expose the test material to the rabbit for 4 hours in the test. I commented on this exposure time because I was concerned about the low pH. It is no longer a concern if the sponsor were to increase the pH value at the lower end. Further, the sensitization test they performed included exposure of the material to guinea pigs for extended periods of time and there was no signs of irritation. I would accept a range of 4.5 to 6 from a biocompatibility standpoint. In the interest of time, you may want to interact with the sponsor and see if they are willing to change the pH range from 3-7 to 4.5-6, which is generally considered the normal pH of human skin. If they , I have no further concerns.

Shelley

From: Grimes, John
Sent: Wednesday, December 21, 2011 10:31 AM
To: Buchen, Shelley
Subject: Biocompatibility Consult: K111717/S002

Shelley,

I just received Supplement 2 for the file you reviewed for me last week (fastest turn around EVER... they got it on the 16th and I got it returned today).

Briefly,

- They revised the pH range to 4 - 6, but I don't know if that's too low or not.
- They did not change the labeling to be 4 hour or less (as we had asked)
- They did not provide any new testing-- neither an increased time to 8 hours, nor provided the pH of the gel actually tested (as we had asked).

The 90th day is 5 Jan 2012. Is there any way you can provide a consult before this date? I am leaving today, but I will be back at work the 29th and 30th.

Please let me know.

Thanks!
Nicky

==========

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

John Grimes, Ph.D.
Biomedical Engineer / Lead Reviewer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic Neurological and ENT Devices
Neurodiagnostic and Neurotherapeutic Devices Branch
[FDA / CDRH / ODE / DONED / NNDB]

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fax: (301)347-8126
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Grimes, John

From: Buchen, Shelley
Sent: Wednesday, December 21, 2011 3:25 PM
To: Grimes, John
Subject: RE: Biocompatibility Consult: K111717/S002

Nicky,

I don't think a formal consult is necessary. Could you just email the sponsor and ask if they would change the pH range of 4.5-6 and be done with it.

Shelley

From: Grimes, John
Sent: Wednesday, December 21, 2011 12:19 PM
To: Buchen, Shelley
Subject: RE: Biocompatibility Consult: K111717/S002

Shelley.

Sounds good. I will scan and e-mail you their S2 as soon as I get done with this other 510k review that's due today.

Thank you!
--Nicky

From: Buchen, Shelley
Sent: Wednesday, December 21, 2011 3:04 PM
To: Grimes, John
Subject: RE: Biocompatibility Consult: K111717/S002

Nicky,

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Grimes, John

From: Grimes, John
Sent: Wednesday, December 21, 2011 3:26 PM
To: Buchen, Shelley
Subject: RE: Biocompatibility Consult: K111717/S002

Shelley,

Sure thing. I already called the sponsor and they said they will check with the managers and see if it's OK, but they don't foresee a problem.

Thank you again for your help!
--Nicky

From: Buchen, Shelley
Sent: Wednesday, December 21, 2011 3:25 PM
To: Grimes, John
Subject: RE: Biocompatibility Consult: K111717/S002

Nicky,

I don't think a formal consult is necessary. Could you just email the sponsor and ask if they would change the pH range of 4.5-6 and be done with it.

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Shelley.

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Thanks!
--Nicky

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Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

COVER SHEET MEMORANDUM

From: Reviewer Name John Grimes

Subject: 510(k) Number K117171SL

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf).			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Rev. 5/12/11

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Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

Review:_____

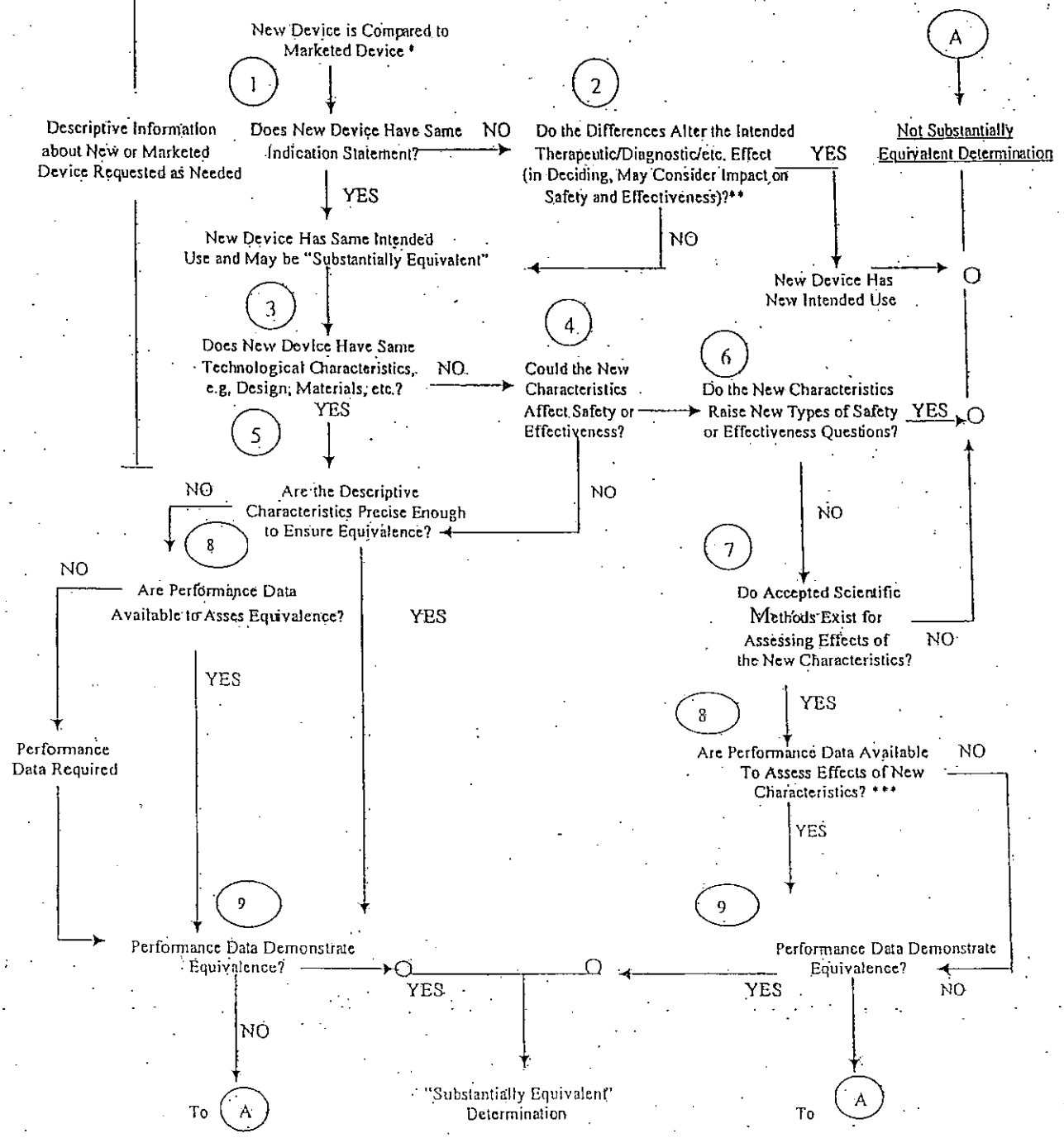
(Branch Chief) (Branch Code) (Date)

Final Review:_____

(Division Director) (Date)

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Hoffmann, Michael

From: Grimes, John
Sent: Friday, December 16, 2011 5:23 PM
To: 'Amy Swallows'
Cc: Hoffmann, Michael
Subject: Request for Additional Information - K111717/S001 - Electro-Gel

Attachments: K111717 - S001 Additional Information Request - December 16 2011.pdf

Dear Ms. Swallows,

In order to complete our review of your submission, Electro-Gel (K111717/S001), we require additional information. Please see the attached Additional Information Request.

K111717 - S001
Additional Info...

Thank you,

==========
John Grimes, Ph.D.
Biomedical Engineer / Lead Reviewer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic Neurological and ENT Devices
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ADDITIONAL INFORMATION REQUESTED FOR K111717

Date: 16 December 2011

Contact: John Grimes, Ph.D.
Biomedical Engineer and Lead Reviewer

To: Amy B. Swallows
Director of Marketing
Electro-Cap International, Inc.
1011 West Lexington Road
Eaton, OH 45320
aswallows@electro-cap.com

Subject: Request for Additional Information – K111717/S001: Electro-Gel

Cc: Record

We have reviewed your response to our July 28, 2011 Request for Additional Information. Although you have adequately addressed deficiencies 4, 6, and 7, we cannot determine if the device is substantially equivalent to a legally marketed predicate device as other issues must still be addressed. Therefore, this 510(k) will be placed on telephone hold. To complete the review of your submission, we require the following information:

Biocompatibility

1. You state that the pH range of the Electro-Gel is 3-7. This range is believed to be too large. Further, a pH of 3 may be irritating to some sensitive individuals. Although your device was found non-irritating to the rabbit in the Irritation Test, the exposure time in that test was only 4 hours versus a maximum exposure time of 8 hours for your device in the human. The specification for the pH of a device should be based on the actual values obtained for the lots used in biocompatibility testing, and a narrow range would help provide assurance that the manufacturing process is well-controlled. Therefore, unless you can provide a scientific justification for the pH specified, please provide us with a new pH specification with a smaller range and a value higher than 3 at the lower end. Additionally, please revise your labelling accordingly.

Device Description

2. In response to prior Deficiency #1, you provide the amounts (by weight) for six of the seven gel solutes. However, you do not specify the concentration of glycerine directly. Please clarify that the amount of glycerine used is 2 gallons, as indicated by your provided manufacturing procedure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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3. In response to prior Deficiency #3, you state that the conductivity of the gel is 0.5 kΩ or less. However, kΩ is the unit of measurement for resistance and impedance (resistance to an alternating current). The unit of measurement for conductance is siemens (S). Please clarify that the impedance of the gel is 0.5 kΩ.

Administrative

4. In response to prior Deficiency #5(c), you provide an updated 510(k) Summary (via Addition 1, received 23 November 2011, and Addition 2, received 1 December 2011). You include the pH range of the gel and the available container sizes. However, you do not include the specific concentrations of the solutes used or the maximum duration of use. Please revise your 510(k) Summary to include the solute concentrations and the maximum duration of use. Please note that concentration is typically provided as a molarity or molality.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

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The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact John Grimes, Ph.D. at john.grimes@fda.hhs.gov or (301)796-2349. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Center for Devices & Radiological Health
Division of Ophthalmic, Neurological, and Ear Nose and Throat Devices

Premarket Notification [510(k)] Review - Traditional
K111717/S001

Date:	**December 16, 2011**
To:	**FILE** John Grimes, Ph.D.
From:	John Grimes, Ph.D., Biomedical Engineer and Lead Reviewer (DONED/NNDB)
Through:	Quynh Hoang MS, Branch chief (DONED/NNDB) 12/16/2011 Malvina Eydelman MD (Division Director, DONED)
Subject:	Review of **Electro-Cap International's** *(sponsor)* Premarket Notification for their *modified* device, the **Electro-Gel** *(device)*.
Contact:	Amy B. Swallows Director of Marketing 1011 West Lexington Rd Eaton, OH 45320 Ph: (937) 456-6099 Fax: (937) 456-7323
Email:	aswallows@electro-cap.com

Summary/Recommendation:

I recommend that this file be PLACED ON HOLD until the sponsor responds with additional information to the Deficiencies presented in Section XV, New Deficiencies, below.

This is a supplement. The review for the original submission was done by Sara Aguel, Biomedical Engineer (DONED/NNDB). Her original comments are denoted within this review as (Original).

The Electro-Gel is a water-soluble, electro-conductive gel intended for use with Electro-Cap International's Electro-Cap device and other non-disposable, recording, external electrodes.

I. Purpose

This is a supplement to previous 510(k) submission K111717 to respond to an additional information request. The 510(k) holder would like to introduce their modified Electro-Gel into interstate commerce.

II. Regulatory History

(Presented by Reviewer of original submission, Sara Aguel, Biomedical Engineer (DONED/NNDB)

Office of Compliance (OC) inspected Electrode-Cap International earlier this year. Among many things, they identified concerns with two formula changes the gel has undergone since last clearance in

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K780045. Specifically (excerpt from e-mail exchange with OC; see attached for full report):

> According to Mr. Hardin, Electro-Gel has undergone two formula changes. Validation was not performed on either change and the firm does not have design control procedures.
>
> Approximately 10-15 years ago, the firm switched from using Phenol Acid in the gel to using Methylparaben and Propylparaben. Mr. Hardin stated that Dr. Ajaz Hussain from the University of Cincinnati did research through literature to determine this change. Dr. Hussain's research is not documented. Mr. Hardin stated that no testing was done to confirm that the gel was still functioning at the same capacity as the previous formula.
>
> A second change was made to the gel approximately three years ago. The firm was originally using Tragacanth, Powder as a component of the gel. The firm discontinued the use of Tragacanth powder and started using TIC Aragum T-1998. TIC Aragum T-1998 is a mixture of Arabic Gum, Guar Gum, and Xanthan Gum manufactured by TIC Gums, 4609 Richlynn Drive, Belcamp, MD 21017. Mr. Hardin stated that the firm provided a jar of Electro-Gel to TIC. According to Mr. Hardin, TIC stated that Aragum T-1998 is the same viscosity as the Tragacanth powder. Mr. Hardin did not have any documentation of testing.
>
> .....
>
> In addition to the components being changed in the formula, the specifications have not been identified. Mr. Hardin stated that the firm does not have any specifications for the viscosity of the gel. The firm measures the viscosity of each batch of gel being manufactured, but there are no specifications to check the results of testing the viscosity. Mr. Hardin stated that he is unsure of the specifications for the conductivity of the gel. Mr.. Hardin stated that the employee who manufactures the gel would not know the specifications for the gel conductivity. A former employee tested the conductivity of the gel until March 2011. Mr. Hardin stated that the firm stopped testing gel conductivity after the employee left the firm. Mr. Hardin stated that there was no variation in the gel conductivity for two years prior to ending the conductivity testing. Mr. Hardin stated that the conductivity specifications were on a quality improvement procedure. Mr. Hardin stated that the results of conductivity testing and the conductivity testing procedure are on the former employees computer. Mr. Hardin was not able to furnish this documentation on 04/20/2011.

OC asked ODE whether the above gel changes warranted a new 510(k). Quynh Hoang and I both responded that yes, a new 510(k) was needed given the changes sine the original clearance could significantly affect the safety and effectiveness of the device. This 510(k) is the sponsor's response to this determination and only their second 510(k) submission.

A search on FDA's public 510(k) database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm) shows that 57 510(k)s have been cleared as "electroconductive media" (under GYB, 882.1275) since 1977. The most recent was cleared in 2004.

A search on FDA's public adverse event/MAUDE database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm) shows that 68 adverse events have been reported under "GYB," a vast majority of them for the Weaver Company's TEN20 conductive paste and Nuprep gel.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) device description

(b)(4) device description

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V. Predicate Devices

The sponsor asserts substantial equivalence to their own Electro-Cap VII System, cleared in **K780045**, and the Weaver TEN20 Conductive Paste (**K883149**).

Though the sponsor does not reference them, other relevant predicates to this review include more recent electroconductive gel clearances such as the Mavidon Medical Electrode Jelly (**K003924**) and Compumedics Quik Gel (**K033052**).

For reference, the cleared Indications for these predicates are outlined below. Those in bold represent the sponsor's identified predicates.

K780045	**Electro-Cap Inc Electro-Cap VII System**	*Prior to IFU Statement, but review memo states:* "An array of prepositioned electrodes arranged in a "hat" to facilitate multi-lead EEG recording. Consists of several parts that are replaceable."
K883149	**Weaver Ten20 Conductive Paste**	*Prior to IFU Statement: Review memo makes no statement of intended use.*
K003924	Mavidon Medical Electrode Jelly	"The Mavidon Medical Electrode Jelly is recommended for use with silver, gold, or tin electrodes in EEG, ECG, EMG, TENS and Muscle Stimulation procedures.
K033052	Compumedics Quik Gel	"The Quik gel is intended to enhance electrical conductivity by facilitating transmission of the electrophysiological signals from the patient to the equipment to reduce impedance at the electrode-to-skin interface. It also helps the Quik cap electrodes adhere to the patient."

Reviewer Comment (Original): The proposed indication is nearly identical to that cleared for the most recent predicate cited above, K033052. The most major differences are the specific references to use in "EEG/EP *recordings*" and "with external electrodes." I find both of these additions adequate as they are consistent with how the sponsor describes the device in other parts of the 510(k) and because they serve to clarify the device's limits of use.

VI. Predicate Comparison

The sponsor submitted a predicate comparison table in Section 3, page 6.

Reviewer Comment (Original): Please see Table 1 below for details of my comparison of the subject device with the above cited predicates. Per my review of the predicate 510(k)s and the differences I note in the table below, my comments are as follows:

- **The sponsor's own previous 510(k), K780045, includes clearance of the Electro-Cap VII System** (which itself consisted of an electrode cap, electrode board harness, body harness, "quick-insert" electrode, disposable sponge disks and needle/syringe "kit"), **"Ear Electrode" and "Electrode Gel." The review memo for this 510(k) is sparse, and only references questions related to the cleaning instructions in *electrode cap's* labeling. I could find little to no detail or review related to the electrode gel.**
- **Reviews of electro-conductive media seem to have become more comprehensive after**

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Electro-Cap's 1978 510(k). For example, in *all* of the 510(k)s I reviewed (from 1988, 2000 and 2003), the sponsor provided (or the reviewer requested) the concentrations of ingredients in the gel (or a manufacturing procedure with specific amounts) and biocompatibility testing. Additionally, two of the three predicates described the pH of the gel. As this precedent is the more recent and more prolific in the regulatory record than K780045, I recommend the sponsor provide this information prior to clearance. It is also important as the composition of the subject Electro-Gel is different from the predicates. See also the Device Description section above and Biocompatibility section below.

- **FDA has recently released DRAFT guidance for Electroconductive Media** (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199256.htm). **This guidance recommends** (in addition to a "written description of all ingredients and concentrations," "identification of the pH in the gel formulation" and biocompatibility testing, as referenced above) **that sponsors "evaluate and document the electroconductive medium's...electrical performance and stability to assure that the device performs as intended." Specifically:**
  - The electroconductive medium should be effective in conducting electrical current across the electrode-skin interface. We recommend that you perform impedance testing to assure that the electroconductive medium has conductive properties that are appropriate for the device's intended use.
  - Electroconductive media should be stable and resist physical and chemical breakdown as a result of conducting electrical current and extended periods of storage over a range of environmental conditions. We recommend that you perform testing to establish, for labeling purposes, the device's shelf life and storage conditions.

While I find the above recommendations scientifically valid, because this guidance is still in draft form (i.e., out for public comment, not yet for implementation) and because it concurrently recommends that electro-conductive media be exempt from 510(k) requirements, I must look to the regulatory precedent for guidance about what is appropriate to ask for in this 510(k).

In my limited review of the 57 devices cleared under the 'electroconductive media" regulation, I found a range of requirements for conductive testing. For example:

- ***K883149*: Sponsor provided a summary of results from conductive testing done in an independent lab (page 10 of response to reviewer questions).**
- ***K003924*: Sponsor provided detailed list of product specifications and** "Performance Standards Certification" **stating the device "meets all its requirements including pH, viscosity, conductivity and ingredient mixture."** ***See attached for a copy of this statement.***
- ***K033052*: No documentation of conductive performance or characteristics, and no request for such data from FDA.**

In this 510(k), the sponsor states "The conducting agent of the gel is Sodium Chloride with a ratio of 30 pounds dissolved in 40 gallons of water has been used for more than 30 years" and "During this period there has never been a customer complaint concerning the conductivity of the gel" **(Original submission, page 8 of 34). Since there is no strong regulatory precedent and because the conductive material is similar to that in at least two other non-Electro-Cap cleared 510(k)s, I do not think it necessary to require the sponsor to provide a summary of results from conductive testing. However, I do recommend the sponsor provide specifications and a signed certification that the gel has been tested and meets its design**

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requirements, "including pH, viscosity, conductivity and ingredient mixture." My rationale for this request is as follows:

- **A lack of "customer complaint concerning the conductivity of the gel" is an inadequate measure of device performance.**
- **OC has noted a lack of conductivity specification and testing in their recent inspection of the sponsor's facilities (see Regulatory History section above an attached e-mail).**
- **There is precedent for this type of documentation for device performance in at least one (relatively) recent predicate 510(k) (K003924).**

- **I have not yet found testing details in predicate 510(k)s related to stability testing, but all three of the predicates referenced above do provide a shelf life (i.e., expiration) in the device labeling. The current sponsor, Electro-Cap, also provides an expiration date (2 years). In order to provide an expiration date, appropriate design controls would include an assessment of the gel's stability up until this date. While I expect this information to be in the sponsor's device master records** (21 CFR 820.3(j)), **because of the lack of regulatory precedent, I will not ask for the sponsor to provide it in the 510(k).**

For my specific recommended deficiencies, see the Deficiencies section below.

Table 1: Comparison of Electro-Gel to Relevant Predicates (**Updated** to reflect S001)

	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
Type of Electrodes Used With	Recording only	Recording	Recording and TENS stimulation electrodes	Recording	Recording only; not for use on "current inducing electrodes"
Ingredients	"commercial lubricating jelly (eg. Lubrafax, K-Y Jelly) with sodium chloride added (approximately one ounce of sodium chloride to 16 ounces of lubricating jelly) to aid in conductivity."	Water Potassium Chloride (conductive) Sodium Chloride (conductive, ionic) "Brij 58" (surfactant) Atlas G-1726 (non-ionic surfactant) Glycerin ("incorporation factor") Calcium carbonate ("calcium compound") 1,2-Propanediol	Water Cullinix 999 Mixing Salt (sodium chloride) Potassium Bitarttrat Glycerine 99% Phenol Cellosize QP – 100M-H Pigment	Distilled Water Potassium Chloride Calcium Chloride Baking Soda ($NaHCO_3$) Gylcerin Soluble Starch ($C_6H_{10}O_5$) Micananzole ($C_{18,}H_{14}C_{14}N_{20}$ HNO_3) Clotrimazole anti-fungal	Water Sodium Chloride (conductive) Aragum T-1998 Powder (viscosity) Potassium Bitartrate (Cream of Tartar) ("improve electrode contact") Glycerin (humectant, preservative, viscosity) Methylparaben (preservative) Propylparaben

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	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
		(propylene glycol) (emulsifier) Gelwhite H (Bentonite) (suspension agent) Dowicil 200 (bacteriostatic agent)			(preservative)
Ingredient concentrations provided?	No	Yes	Yes	Step-by-step procedure followed to formulate gel – including amounts, timing, temps – provided (Att E)	Yes* *Glycerine omited
pH of gel formation	*unknown*	6.00 to 6.50	7 +/- 0.5	*unknown*	3 – 7
Duration of Use	*unclear*		1 hour	*unclear*	Maximum of 8 hours
Biocomp-atibility Testing provided?	No	**Yes, of final product** – skin irritation. Also provided chemical and toxicity information on individual ingredients (Brij 58, Atlas G 1726, Dowicil 200, Gelwhite H)	**Yes, of final product** –skin irritation, dermal sensitization, cytotoxicity	**Yes, of final product** - irritation, sensitization, dermal sensitization, cytotoxicity,	**Yes.** Agar Diffusion Test ISO 10993-5,-12 Primary Skin Irritation Test-ISO Direct Contact ISO 10993-10,-12 and Buehler Sensitidation Test ISO 10993-10,-12
Impedance Testing?	None provided	**Yes** – testing done by independent lab; gel impedance is between 1-3 kOhms	No specific protocols provided, but Specifications provided and a "Performance Standards Certification" that states device "meets all its requirements including pH,	None provided	Design specifications and certification statement that the gel has been tested and meets the specifications 0.5 kΩ or less*

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	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
			viscosity, conductivity and ingredient mixture"		*Listed as Conductivity, but incorrect units.
Shelf life	*unknown*	"Product lot # and expiration date will be displayed on each container"	6 months	"The expiration date is on the bottom of each bottle"	2 years, "provided the gel is stored in the original container at room temperature with lid tightly closed."
Storage conditions	*unknown*	"Keep lid closed when not in use. Room temperature."	*unknown*	*unknown*	Room temperature; original container; lid tightly closed

VII. Performance Testing

a. Bench and Clinical

Related to performance testing, the sponsor states the following (page 8, yellow highlight added):

> There are no known formal performance standards which apply to the product, but we maintain that the efficacy of the product for its intended use has been demonstrated in the market place, and Electro-Gel's dominant market share. The amount of the 2008 formulated Electro-Gel that has been sold was enough to record more than 10,000,000 EEG's with only one known minor incident reported would also support this claim.
>
> The following comments are also provided as a means of clarification:
>
> **Contact Duration**
> A clinical EEG test will last approximately two hours however brain monitoring during surgery last for several hours. The Electro-Gel is also used in sleep studies for up to 8 hours. There have no reported incidents of adverse skin reaction in any of these situations. Accordingly the contact duration would be in excess of 8 hours.
>
> **Electrical Performance**
> The conducting agent of the gel is Sodium Chloride with a ratio of 30 pounds dissolved in 40 gallons of water has been used for more than 30 years. During this period there has never been a customer complaint concerning the conductivity of the gel.
>
> **Stability**
> Shelf life is 2 years, provided the gel is stored in the original container at room temperature with the lid tightly closed.

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The sponsor also submitted an excerpt of pictures from one article in which the Electro-Gel was used on astronauts in space (Attachment A).

The sponsor has submitted no bench or clinical data in this 510(k).

Reviewer Comment (Original): The sponsor has not adequately addressed performance testing issues for their device. Pictures of astronauts using the gel in space (Attachment A) and assertions that efficacy has been proven in the marketplace because their have been no complaints or major incidents is insufficient.

Please see the Predicate Comparison above for my recommendations as they relate to conductivity and stability testing.

For my specific recommended deficiencies, see the Deficiencies section below.

Reviewer Comment:
The sponsor provided the requested design specifications and certification statement that the gel meets the specifications.

b. Electrical and EMC Safety

Not applicable. Device does not include any electronic components.

c. Software

Not applicable. Software is not a part of this device or 510(k).

VIII. Sterilization

Not applicable. Device not provided sterile (Original submission, page 7).

IX. Biocompatibility

Related to biocompatibility, the sponsor states the following (page 7, yellow highlight added):

> The Electro-Gel is made from known biocompatible (food grade) materials. The only known instance of bioincompatibility involved one 5 month old pediatric patient in 2011 who suffered minor skin abrasions when the EEG test lasted for 24 hours. The two electrode sites on the back of the scalp, where pressure would have been applied while the child was on its back, were the only 2 of 10 sites affected. It was suggested to our distributor in Japan that the probable cause was the long exposure to the sodium chloride in the gel. The distributor agreed and the customer complaint was closed.
>
> No other reaction to the gel has been recorded during the past 23 years the Electro-Gel has been used.

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As such, we maintain that the biocompatibility of the product has been strongly demonstrated and we maintain that formal testing to ISO 10993-1 would add no value.

Reviewer Comment (Original): The sponsor has not adequately addressed biocompatibility issues for their device. Use for "past 23 years" and lack of recorded incidents (except one) is an insufficient replacement to formal testing to ISO 10993-1. This is especially true given the following:

- **All the more recent predicates I reviewed (K883149, K003924, K033052) included biocompatibility testing for skin irritation and the latter (more recent) two of them included tests for sensitization and cytotoxicity.**
- **Per my informal conversation with Molly Ghosh PhD, it is important to understand how the gel ingredients react together in the final product. Dr. Ghosh helped me draft the deficiency for the sponsor. See attached e-mails.**

For my specific recommended deficiency, see the Deficiencies section below.

Reviewer Comment:
The sponsor provided biocompatibility testing. However, questions have been raised concerning both the broad pH range (3 – 7) and duration of use vs. test duration. Specifically, the pH range is thought to be too low and the duration is listed at a maximum of 8 hours, but testing only lasted 4 hours. Please see the attached biocompatibility consult from Shelley Buchen, attached, and Section XIV, New Deficiencies, below.

X. Labeling

The sponsor provided their proposed labeling in Attachment C of the submission.

The sponsor lists the following important items in their labeling:

- List of ingredients
- Storage instructions
- Storage instructions: "Keep containers tightly closed and at room temperature."
- Expiration: "Expiration data is found on the bottom of the jar"
- "For External Use Only"
- "Use topically on healthy, intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury on the medical condition of the patient."
- "Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions."
- "If rash, redness, itching, swelling, or abnormality appears on skin, wash off immediately. Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites."
- "Avoid eye contact."
- "Do not use with current inducing electrodes."
- "Keep out of the reach of children."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Reviewer Comment (Original): I recommend the labeling add the following:
- **Maximum duration of use**
- **How to remove the gel from the electrode and skin following use**
- **Caution that gel should not be reused.**
- **IFU ("Usage") statement modified to be identical to that stated on the IFU statement.**

For my specific recommended deficiency, see the Deficiencies section below.

Reviewer Comment:
The sponsor provided updated labeling, as requested.

XI. Substantial Equivalence Discussion

Not applicable at this time. Recommendation is for AI.

XII. Administrative Requirements

	Yes	No
Indications for Use page (**Prescription**)	X	
Truthful and Accuracy Statement	X	
510(k) Summary or 510(k) Statement	X	
Standards Form		X
ClinicalTrials.gov Certification form		X

Reviewer Comment (Original): The sponsor only references quality systems standards in the 510(k), to which I don't believe a Standards Form is required. Though one will be needed if they state conformance to the biocompatibility standard ISO 10993. Additionally, the 510(k) Summary is missing some important information (e.g., other predicates, performance testing summary) and there is no ClinicalTrials.gov certification form.

XIII. Sponsor Response to Deficiencies

The original Deficiency is presented in *italics*
The sponsor's response is presented in underlined text
Reviewer comments are presented in **bold**

Device Description

1. *Your provided device description is incomplete. Please provide additional information regarding the following:*
    a. *Specific concentrations of ingredients*

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(b)(4) device description

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with short term skin contact. If identical materials are used in any legally marketed medical devices with same nature and duration of contact, you can identify those devices instead of conducting biocompatibility testing. However, please note that we only consider the materials to be identical if they have the same chemical formulations, same manufacturing processes and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc).

21 CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following tests: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,-12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests. Copies of test reports attached.

Electro-Gel is tested internally for pH, conductivity and viscosity on a regular basis.

The tests only lasted a maximum of 4 hours. See Biocompatibility Consult from Shelley Buchen, attached, and Section XIV, New Deficiencies, below.

3. *You have not adequately addressed performance testing for your device. You justified omission of testing with reference to the large amount of gel sold and lack of reported complaints, but this is insufficient. Isolated case reports and random experience do not constitute valid scientific evidence (21 CFR 860.7(c)(2)). You do not need to submit testing reports, protocols or results in this 510(k) for your device. However, to ensure this testing has been completed, please provide your design specifications for pH, viscosity, conductivity and ingredient mixture and a signed certification statement that your final gel has been tested for these specifications and meets all of its requirements.*

   You will find attached our design specifications for pH, viscosity, conductivity and ingredient mixture, along with our certification statement that the gel has been tested and meets these specifications.

   This is acceptable.

Labeling

4. *You provided labeling in Attachment C of your 510(k). To ensure users know how to safely and effectively use your device, please add the following information to your labeling:*
   a. *Maximum duration of use*
   b. *How to remove the gel from the electrode and skin following use*
   c. *Gel should not be reused.*
   d. *"Usage" statement modified to be identical to that of your submitted Indications for Use (IFU) statement*

   Attachment C has been revised to incorporate the requested information.

   This is acceptable.

Administrative

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

5. *Please revise your 510(k) Summary to meet the requirements outlined in 21 CFR 807.92 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92) and the following specific concerns:*

We have revised the 510(k) summary as requested and attached it with this correspondence.

a. *Please provide a more detailed predicate comparison (e.g., predicate comparison table). Please also add more recent and relevant predicates to your list, such as K003924 and K033052.*

We have updated our original predicate device table, and have added a second table which includes the additional predicates as requested.

This is acceptable.

b. *Please add a summary of your completed device testing, e.g. those related to biocompatibility and conductivity.*

We have added a section for Device Testing in our 510(k) summary.

This is acceptable.

c. *Please add the device description information requested in the deficiency above.*

We have added the device description information to the 510 (k) as requested.

The sponsor omitted the solute concentrations and the maximum duration of use. See Section XIV, New Deficiencies, below.

6. *The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that all original 510(k)s submitted on or after December 26, 2007 (90 days after the enactment date of FDAAA) be accompanied by certification that they are in compliance with the requirements of Title 8 of FDAAA. To meet the requirements of this certification, please submit the following form entitled 'The Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank Form which is available at the following weblink: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf. Please also see CDRH's related guidance at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.*

Form FDA 3674, Certificate of Compliance, under 42 U.S.C. is attached.

This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7. *FDA encourages you to provide an electronic copy of your submission response. Please refer to our Center web page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm for the latest update of instructions for providing electronic submissions.*

   We have reviewed the information regarding electronic submissions.

   This is acceptable.

XIV. New Deficiencies

Biocompatibility

1. You state that the pH range of the Electro-Gel is 3-7. This range is believed to be too large. Further, a pH of 3 may be irritating to some sensitive individuals. Although your device was found non-irritating to the rabbit in the Irritation Test, the exposure time in that test was only 4 hours versus a maximum exposure time of 8 hour for your device in the human. The specification for the pH of a device should be based on the actual values obtained for the lots used in biocompatibility testing and a narrow range would help provide assurance that the manufacturing process is well controlled. Therefore, unless you can provide a scientific justification for the pH specified, please provide us with a new pH specification with a smaller range and a value higher than 3 at the lower end, and revise your labelling accordingly.

Device Description

2. In response to prior Deficiency 1, you provided the amounts (by weight) for six of the seven gel solutes. However, you did no specify the concentration of glycerine directly. Please clarify that the amount of glycerine used is 2 gallons, as indicated by your provided manufacturing procedure.

3. In response to prior Deficiency 3, you state that the conductivity of the gel is 0.5 kΩ or less. However, kΩ is the unit of measurement for resistance and impedance (resistance to an alternating current). The unit of measurement for conductance is siemens (S). Please clarify that the impedance of the gel is 0.5 kΩ.

Administrative

4. In response to prior Deficiency 5 part c, you provided an updated 510(k) Summary (via Addition 1, received 23 November 2011, and Addition 2, received 1 December 2011). You included the pH range of the gel and the available container sizes. However, you did not include the specific concentrations of the solutes used or the maximum duration of use. Please revise your 510(k) Summary to include the solute concentrations and the maximum duration of use. Please note that concentration is typically provided as a molarity or molality.

XV. Consults

I informally consulted with Molly Ghosh PhD (DONED/NNDB) about biocompatibility issues. She raised concerns about the pH ranges and testing provided. However, she did not have sufficient time

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to provide a full review. Shelley Buchen provided a biocompatibility consult

XVI. Contact History

The only contact with the sponsor was to respond to questions via e-mail concerning whether the needed to submit additions to the DMC and to status requests on their file.

XVII. Recommendation

As outlined above, this submission requires additional information before a final decision can be reached. I recommend this device go ON HOLD until this information is received from the sponsor.

John Grimes, Ph.D., Biomedical Engineer and Lead Reviewer **(12/16/2011)**
Neurodiagnostic and Neurotherapeutic Branch
Division of Ophthalmic, Neurological and ENT Devices

Attachments:

- Biocompatibility consult from Shelley Buchen.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Consulting Review Memorandum

Date: December 15, 2011

From: Shelley Buchen

Subject: K111717S001
Electro-Gel
Biocompatibility Review

To: The Record

Through: John Grimes

Sponsor: Electro-Cap International, Inc.
Eaton, OH

Device Description and Background

(b)(4) device description

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Intended Use of Device

Electro-Gel is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Predicate Devices

Electro-Gel (K780045)
Electro-Cap International, Inc.

TEN20 Conductive Paste (K883149)
Weaver and Company

Mavidon Electrode Jelly (K003924)
Mavidon

Quick Gel (K033052)
Compumedics

Biocompatibility Assessment

The sponsor completed the following biocompatibility tests on Electro-Gel in accordance with the recommendations in FDA's Blue Book memorandum G95-1 and ISO 10993-1 as requested by the FDA.

Agar Diffusion Test, ISO 10993-5,-12
Primary Skin Irritation Test-ISO, Direct Contact, ISO 10993-10
Buehler Sensitization Test, ISO 10993-10

The tests were performed at Toxikon in accordance with Good Laboratory Practice and the corresponding ISO standards. The results are unremarkable. The gel was found to be non-irritating, non-cytotoxic and non-sensitizing.

I am, however, concerned about the wide pH range (3-7) of the gel specified by the sponsor. Although an electrode gel with a pH 3 is not necessarily irritating because the pH of skin care products on the market generally range from 3 to 7, it could be irritating for some sensitive individuals. Further, a narrower range would help provide assurance that the process is well controlled. I would recommend that the sponsor tighten the specification and raise the pH at the lower end unless a scientific justification can be given.

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Conclusion and Recommendation

The sponsor completed testing as requested by FDA to support the biocompatibility of the Electro-Gel when used as intended. However, a pH range of 3-7 is believed to be too large and the lower end value too low unless a scientifically valid justification can be given. Please provide the following comment to the sponsor.

> *You state that the pH range of the Electro-Gel is 3-7. This range is believed to be too large. Further, a pH of 3 may be irritating to some sensitive individuals. Although your device was found non-irritating to the rabbit in the Irritation Test, the exposure time in that test was only 4 hours versus a maximum exposure time of 8 hour for your device in the human. The specification for the pH of a device should be based on the actual values obtained for the lots used in biocompatibility testing and a narrow range would help provide assurance that the manufacturing process is well controlled. Therefore, unless you can provide a scientific justification for the pH specified, please provide us with a new pH specification with a smaller range and a value higher than 3 at the lower end, and revise your labelling accordingly.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Sara Aguel

Subject: 510(k) Number K111717/~~S1~~ A1

To: The Record

Please list CTS decision code _____

x Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

x Hold (Additional Information or Telephone Hold).

x Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

x	NO	NSE for lack of predicate
x	NI	NSE for new intended use
x	NQ	NSE for new technology that raises new questions of safety and effectiveness
x	NP	NSE for lack of performance data
x	NM	NSE requires PMA
x	NS	NSE no response
x	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

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Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

_____

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

Review:_____

(Branch Chief) (Branch Code) (Date)

Final Review:_____

(Division Director) (Date)

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Aguel, Sara D

From: Aguel, Sara D
Sent: Wednesday, August 17, 2011 5:42 PM
To: 'Amy Swallows'
Cc: Hoffmann, Michael; Hoang, Quynh T.
Subject: RE: Additional information for K111717

Ms. Swallows,
Today I received the hard copy of the letter you referenced in your August 15 e-mail below. It was logged in as a supplement. However, as I explained to you in my August 16, 2011 e-mail below, we cannot accept partial responses to our AI letters.

In your current response to Deficiency #2, you state that "test results should be available in eight to ten weeks." We consider this an incomplete response. In order for your submission to be reviewed in full, please provide the *completed* biocompatibility testing data on your final device that we requested in Deficiency #2.

Again, because of your incomplete response, we are converting your submission to an amendment (A1) to your original application. Please note that your submission still remains on hold as of the **original hold date** (July 28, 2011). Please see our e-mail dated July 28, 2011 for instructions regarding your time to respond and how to submit requests for additional time to respond.

When you have completed your biocompatibility testing, please submit your *entire* response to our July 28, 2011 AI letter.

If you have any questions about any of the above, please let me know.

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
US Food and Drug Administration

E-mail: sara.aguel@fda.hhs.gov
Phone #: (301) 796-6494
Fax #: (301) 847-8126

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the intended recipient, you are hereby notified that any disclosure, dissemination, distribution, copying, or other action based on the content of this communication is NOT AUTHORIZED. If you have received this document in error, please immediately notify Sara Aguel by email at sara.aguel@fda.hhs.gov or telephone at 301-796-6494.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Amy Swallows [mailto:aswallows@electro-cap.com]
Sent: Tuesday, August 16, 2011 10:14 AM
To: Aguel, Sara D
Subject: RE: Additional information for K111717

Dear Ms. Aguel,

Thank you for your message, and for the clarification. We will send a separate letter today to the address noted in your letter to us dated 7/28/11, to request an extension for the submission of the response.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Best regards,
Amy Swallows

From: Aguel, Sara D [mailto:Sara.Aguel@fda.hhs.gov]
Sent: Tuesday, August 16, 2011 9:17 AM
To: 'Amy Swallows'
Subject: RE: Additional information for K111717

Ms. Swallows,
It's unclear to me from your e-mail whether you are requesting an extension for your hold or responding to the AI letter. You cannot do both at the same time. We do not review responses to AI letters until you are able to provide a response to the entire letter. If your S1 response is incomplete (i.e., you do not respond to each of the deficiencies in the AI letter, you do not have *completed* biocompatibility test results), we will deem your S1 response "inadequate incoming" and place it back on hold.

Since you will not get your biocompatibility results for 8-10 weeks, I can only assume your submitted letter represents an incomplete response. Therefore, I recommend you submit *only* a request for extension of your hold at this time.

If you have questions about this, please let me know.

Kind Regards,

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation

US Food and Drug Administration

E-mail: sara.aguel@fda.hhs.gov
Phone #: (301) 796-6494
Fax #: (301) 847-8126

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From: Amy Swallows [mailto:aswallows@electro-cap.com]
Sent: Monday, August 15, 2011 3:28 PM
To: Aguel, Sara D
Cc: jfz@SpectraMedEx.com
Subject: Additional informaton for K111717

Dear Ms. Aguel,

Thank you for talking with our consultant, John Ziobro, the other day. We appreciate your cooperation.

We are sending a letter to you today addressing the additional information, with the appropriate attachments. We have noted in the appropriate places that we have just

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begun the process of having the Electro-Gel tested for biocompatibility at an independent laboratory, and have been advised that test results will not be available for approximately 8 - 10 weeks. Accordingly, we are requesting an extension for the submission of the information; we will revise the information for device testing and the product summary as soon as we have received the test results.

If you have any questions concerning any of the information submitted with the letter, or if we need to submit our request for an extension differently, please let us know.

Best regards,
Amy Swallows

Electro-Cap International, Inc.
Amy Swallows
Director of Marketing
Eaton, OH, USA
TEL: 800 527-2193
FAX: 937 456-7323
email: eci@electro-cap.com
or: aswallows@electro-cap.com
www.electro-cap.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Sara Aguel

Subject: 510(k) Number K111717

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Rev. 5/12/11

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Hoang (Branch Chief) NNDB (Branch Code) 7/28/11 (Date)

Final Review:

(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Hoang, Quynh T.

From: Aguel, Sara D
Sent: Thursday, July 28, 2011 4:43 PM
To: 'aswallows@electro-cap.com'
Cc: Hoang, Quynh T.
Subject: K111717
Attachments: K111717 ElectroCap Electro-Gel - AI Letter FINAL.pdf

Ms. Swallows,
I am the lead reviewer of the above referenced 510(k). Please find attached FDA's request for additional information for K111717. As of today, we consider this 510(k) to be on hold, pending your response to the deficiencies outlined in the letter.

If you have questions about anything in this letter, please feel free to contact me for clarification on what we have requested.

Kind Regards

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
US Food and Drug Administration

E-mail: sara.aguel@fda.hhs.gov
Phone #: (301) 796-6494
Fax #: (301) 847-8126

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

ADDITIONAL INFORMATION REQUESTED FOR K111717

Date: July 28, 2011

Contact person: Sara Aguel, Lead Reviewer (DONED/NNDB)

To: Amy B. Swallows
Director of Marketing
Electro-Cap International
1011 West Lexington Rd
Eaton, OH 45320
aswallows@electro-cap.com

Subject: Additional information requested / Telephone hold for K111055 for Electro-Gel

Cc: Record

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we will require your response to the following:

Device Description

1. Your provided device description is incomplete. Please provide additional information regarding the following:

    a) Specific concentrations of ingredients

    b) Maximum duration of use

    c) pH range

    d) Available container sizes

Device Testing

2. You have not conducted any biocompatibility testing on your device. You justified this omission of testing by stating that you use "food grade" materials and that you have sold a large amount of gel and haven't received any complaints, but this is insufficient. We recommend that biocompatibility testing be conducted on the finished device because biocompatibility of a final device depends not only on the materials used for manufacturing of the device but also on any new chemical entity that could potentially be formed due to interactions of these materials, the processing of the materials,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

manufacturing method and manufacturing residuals that may be imparted on the final device. Thus, please provide biocompatibility data on your final device. FDA's Blue Book memorandum G95-1 recommends that cytotoxicity, irritation, and sensitization testing be considered for devices with short term skin contact. If identical materials are used in any legally marketed medical devices with same nature and duration of contact, you can identify those devices instead of conducting biocompatibility testing. However, please note that we only consider the materials to be identical if they have the same chemical formulations, same manufacturing processes and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc).

3. You have not adequately addressed performance testing for your device. You justified omission of testing by stating that you have sold a large amount of gel and haven't received any complaints, but this is insufficient. Isolated case reports and random experience do not constitute valid scientific evidence (21 CFR 860.7(c)(2)). You do not need to submit testing reports, protocols or results in this 510(k) for your device. However, to ensure this testing has been completed, please provide your design specifications for pH, viscosity, conductivity and ingredient mixture and a signed certification statement that your final gel has been tested for these specifications and meets all of its requirements.

Labeling

4. You provided labeling in Attachment C of your 510(k). To ensure users know how to safely and effectively use your device, please add the following information to your labeling:

   a) Maximum duration of use

   b) How to remove the gel from the electrode and skin following use

   c) Gel should not be reused.

   d) "Usage" statement modified to be identical to that of your submitted Indications for Use (IFU) statement

Administrative

5. Please revise your 510(k) Summary to meet the requirements outlined in 21 CFR 807.92 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92) and the following specific concerns:

   a) Please provide a more detailed predicate comparison (e.g., predicate comparison table). Please also add more recent and relevant predicates to your list, such as K003924 and K033052.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

b) Please add a summary of your completed device testing, e.g. those related to biocompatibility and conductivity.

c) Please add the device description information requested in the deficiency above.

6. The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that all original 510(k)s submitted on or after December 26, 2007 (90 days after the enactment date of FDAAA) be accompanied by certification that they are in compliance with the requirements of Title 8 of FDAAA. To meet the requirements of this certification, please submit the following form entitled 'The Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank Form which is available at the following weblink: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf. Please also see CDRH's related guidance at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.

7. FDA encourages you to provide an electronic copy of your submission response. Please refer to our Center web page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm for the latest update of instructions for providing electronic submissions.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue.
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Sara Aguel at (301) 796-6494 or sara.aguel@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Center for Devices & Radiological Health
Division of Ophthalmic, Neurological, and Ear Nose and Throat Devices

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Premarket Notification [510(k)] Review - Traditional
K111717

Date:	**July 28, 2011**
To:	**FILE**
From:	Sara Doll Aguel, Biomedical Engineer (DONED/NNDB)
Through:	Quynh Hoang MS, Branch chief (DONED/NNDB) QHoang 7/28/11 Malvina Eydelman MD (Division Director, DONED)
Subject:	Review of **Electro-Cap International's** *(sponsor)* Premarket Notification for their *modified* device, the **Electro-Gel** *(device)*.

Contact:	Amy B. Swallows Director of Marketing 1011 West Lexington Rd Eaton, OH 45320 Ph: (937) 456-6099 Fax: (937) 456-7323
Email:	aswallows@electro-cap.com

Summary/Recommendation:

The Electro-Gel is a water-soluble, electro-conductive gel intended for use with Electro-Cap International's Electro-Cap device and other non-disposable, recording, external electrodes.

I have reviewed this submission, as well as the sponsor's two identified predicates and two additional predicates of my own choosing. In summary, I recommend Electro-Cap International respond to the following concerns:

- The device description is incomplete. The sponsor should provide additional information regarding specific concentrations of ingredients, maximum duration of use, pH range, and available container sizes.
- The sponsor provided no biocompatibility testing, but as a patient-contacting material, this is required prior to clearance. *This request is consistent with requirements of nearly all predicates I reviewed, with Electro-Cap's own 1978 510(k) being the only exception*).
- The sponsor inadequately addressed conductivity testing. The sponsor should provide their design specifications and a signed "Certification" that the gel has been tested for the specifications and meets all of its requirements." *This request is consistent with at least one predicate, K003924, and less burdensome than that provided in another predicate (K883149).*
- The 510(k) Summary should be modified to add the two additional predicates I used in my assessment and a summary of performance testing (e.g., biocompatibility, conductivity).

Due to the above outstanding concerns, I recommend this 510(k) go TELEPHONE HOLD until **additional information** is received from the sponsor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

I. Purpose

The 510(k) holder would like to introduce their modified Electro-Gel into interstate commerce.

II. Regulatory History

Office of Compliance (OC) inspected Electrode-Cap International earlier this year. Among many things, they identified concerns with two formula changes the gel has undergone since last clearance in K780045. Specifically (excerpt from e-mail exchange with OC; see attached for full report):

> According to Mr. Hardin, Electro-Gel has undergone two formula changes. Validation was not performed on either change and the firm does not have design control procedures.
>
> Approximately 10-15 years ago, the firm switched from using Phenol Acid in the gel to using Methylparaben and Propylparaben. Mr. Hardin stated that Dr. Ajaz Hussain from the University of Cincinnati did research through literature to determine this change. Dr. Hussain's research is not documented. Mr. Hardin stated that no testing was done to confirm that the gel was still functioning at the same capacity as the previous formula.
>
> A second change was made to the gel approximately three years ago. The firm was originally using Tragacanth, Powder as a component of the gel. The firm discontinued the use of Tragacanth powder and started using TIC Aragum T-1998. TIC Aragum T-1998 is a mixture of Arabic Gum, Guar Gum, and Xanthan Gum manufactured by TIC Gums, 4609 Richlynn Drive, Belcamp, MD 21017. Mr. Hardin stated that the firm provided a jar of Electro-Gel to TIC. According to Mr. Hardin, TIC stated that Aragum T-1998 is the same viscosity as the Tragacanth powder. Mr. Hardin did not have any documentation of testing.
>
> .....
>
> In addition to the components being changed in the formula, the specifications have not been identified. Mr. Hardin stated that the firm does not have any specifications for the viscosity of the gel. The firm measures the viscosity of each batch of gel being manufactured, but there are no specifications to check the results of testing the viscosity. Mr. Hardin stated that he is unsure of the specifications for the conductivity of the gel. Mr.. Hardin stated that the employee who manufactures the gel would not know the specifications for the gel conductivity. A former employee tested the conductivity of the gel until March 2011. Mr. Hardin stated that the firm stopped testing gel conductivity after the employee left the firm. Mr. Hardin stated that there was no variation in the gel conductivity for two years prior to ending the conductivity testing. Mr. Hardin stated that the conductivity specifications were on a quality improvement procedure. Mr. Hardin stated that the results of conductivity testing and the conductivity testing procedure are on the former employees computer. Mr. Hardin was not able to furnish this documentation on 04/20/2011.

OC asked ODE whether the above gel changes warranted a new 510(k). Quynh Hoang and I both responded that yes, a new 510(k) was needed given the changes sine the original clearance could significantly affect the safety and effectiveness of the device. This 510(k) is the sponsor's response to this determination and only their second 510(k) submission.

A search on FDA's public 510(k) database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm) shows that 57 510(k)s have been cleared as "electroconductive media" (under GYB, 882.1275) since 1977. The most recent was cleared in 2004.

A search on FDA's public adverse event/MAUDE database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm) shows that 68 adverse events have been reported under "GYB," a vast majority of them for the Weaver Company's TEN20 conductive paste and Nuprep gel.

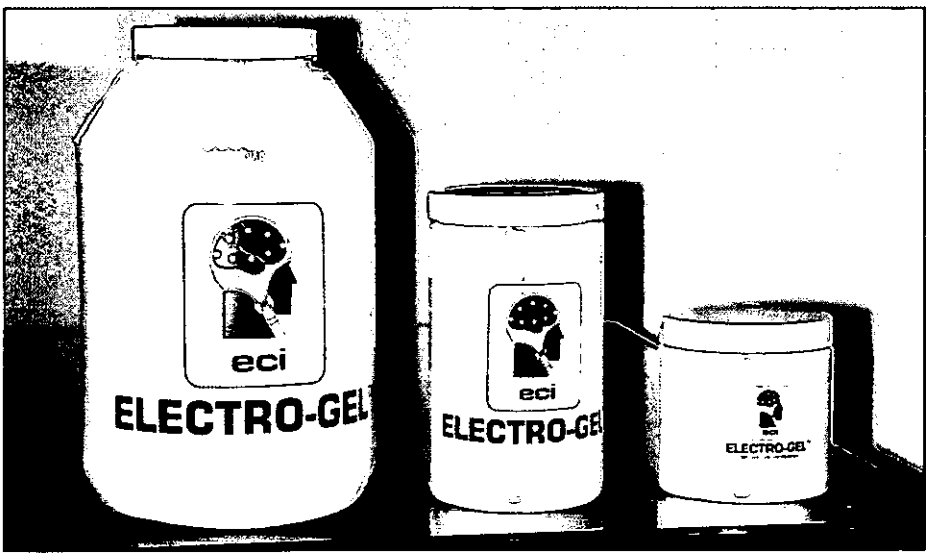
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	
Is the device an implant (implanted longer than 30 days)?		N	
Does the device design use software?		N	
Is the device sterile?		N	
Is the device reusable (not reprocessed single use)?		N	
Are "cleaning" instructions included for the end user?			X

Of Note: The below device description is copied almost identically from the submitted Device Description section (Section 1.0 – pages 1-2 of the original submission) and supplemented with information from other parts of the submission (where noted).



Electro-Gel is an off white color, water-miscible conductive gel intended for use with the Electro-Cap and other non-disposal neurodiagnostic electrodes including ECG and EMG electrode applications. It is water soluble and can be easily and completely washed from the head with water and shampoo.

Electro-Gel serves as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the electroencephalogram or computer equipment. Electro-Gel is for use with external electrodes only.

Electro-Gel is a mixture of the following "food grade" (page 7 of 34) components:

1. **Water**: Tap water. *Function = vehicle.*
2. **Sodium Chloride**: Morton's culinox 999 chemical grade salt. *Function = conductance.*
3. **Aragum T-1998 Powder**: Gum Acacia, Guar Gum and Xanthan Gum. *Function = viscosity.*
4. **Potassium Bitartrate**: (Cream of Tartar), Powder NF/FCC. *Function = improve electrode contact.*
5. **Glycerin**: Glycerine 99.7% USP Kosher. *Function = humecant, preservative and viscosity.*
6. **Methylparaben**: NF. *Function = preservative.*

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7. **Propylparaben**: USP. *Function = preservative.*

The Electro-Gel was manufactured with the same formula received with the purchase of the company **until 1991** when the preservatives, Methylparaben and Propylparaben, replaced Phenol.

The original formula contained Tragacanth, a water–soluble carbohydrate gum used as a thickening and stabilizing agent. Tragacanth is harvested from plants in Iran and the Middle East and due to troubled diplomatic relations it became very difficult to obtain a steady supply. Accordingly, other gums such as Aragum T-1998 have replaced Tragancanth in food, cosmetic and drug products and was selected by Electro-Cap as the **replacement for Tragacanth in 2008**.

Contact Duration: "...the contact duration would be in excess of 8 hours" (page 8 of 34).

The sponsor also states (Device Labeling, Attachment C) that the gel should **not be used with** current inducing electrodes.

Reviewer Comment (Original): The amount of detail the sponsor has provided about their gel is inconsistent with that provided for relevant predicates (see Predicate Comparison section below). I recommend the sponsor provide additional description of the following:

- **Specific concentrations of ingredients**
- **The size containers in which the gel is available**
- **The 510(k) states contact duration of the gel could be "in excess of 8 hours." This is insufficient. The sponsor should clarify the contact duration, specifically identifying a maximum time limit.**
- **pH range of the gel**

For my specific recommended deficiencies, see the Deficiencies section below.

IV. Proposed Indication for Use

The sponsor proposes the Electro-Gel be indicated for the following (Attachment B; **bold** emphasis added):

> Electro-Gel is intended for use in clinical and research EEG/EP **recordings** from humans. It is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

Reviewer Comment (Original): No comment at this time. See "Predicate Device" section below.

V. Predicate Devices

The sponsor asserts substantial equivalence to their own Electro-Cap VII System, cleared in **K780045**, and the Weaver TEN20 Conductive Paste (**K883149**).

Though the sponsor does not reference them, other relevant predicates to this review include more

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recent electroconductive gel clearances such as the Mavidon Medical Electrode Jelly (**K003924**) and Compumedics Quik Gel (**K033052**).

For reference, the cleared Indications for these predicates are outlined below. Those in bold represent the sponsor's identified predicates.

K780045	**Electro-Cap Inc Electro-Cap VII System**	*Prior to IFU Statement, but review memo states:* "An array of prepositioned electrodes arranged in a "hat" to facilitate multi-lead EEG recording. Consists of several parts that are replaceable."
K883149	**Weaver Ten20 Conductive Paste**	*Prior to IFU Statement; Review memo makes no statement of intended use.*
K003924	Mavidon Medical Electrode Jelly	"The Mavidon Medical Electrode Jelly is recommended for use with silver, gold, or tin electrodes in EEG, ECG, EMG, TENS and Muscle Stimulation procedures.
K033052	Compumedics Quik Gel	"The Quik gel is intended to enhance electrical conductivity by facilitating transmission of the electrophysiological signals from the patient to the equipment to reduce impedance at the electrode-to-skin interface. It also helps the Quik cap electrodes adhere to the patient."

Reviewer Comment (Original): The proposed indication is nearly identical to that cleared for the most recent predicate cited above, K033052. The most major differences are the specific references to use in "EEG/EP *recordings*" and "with external electrodes." I find both of these additions adequate as they are consistent with how the sponsor describes the device in other parts of the 510(k) and because they serve to clarify the device's limits of use.

VI. Predicate Comparison

The sponsor submitted a predicate comparison table in Section 3, page 6.

Reviewer Comment (Original): Please see Table 1 below for details of my comparison of the subject device with the above cited predicates. Per my review of the predicate 510(k)s and the differences I note in the table below, my comments are as follows:

- **The sponsor's own previous 510(k), K780045, includes clearance of the Electro-Cap VII System** (which itself consisted of an electrode cap, electrode board harness, body harness, "quick-insert" electrode, disposable sponge disks and needle/syringe "kit"), **"Ear Electrode" and "Electrode Gel." The review memo for this 510(k) is sparse, and only references questions related to the cleaning instructions in *electrode cap's* labeling. I could find little to no detail or review related to the electrode gel.**
- **Reviews of electro-conductive media seem to have become more comprehensive after Electro-Cap's 1978 510(k). For example, in *all* of the 510(k)s I reviewed (from 1988, 2000 and 2003), the sponsor provided (or the reviewer requested) the concentrations of ingredients in the gel (or a manufacturing procedure with specific amounts) and biocompatibility testing. Additionally, two of the three predicates described the pH of the gel. As this precedent is the more recent and more prolific in the regulatory record than K780045, I recommend the sponsor provide this information prior to clearance. It is also important as the composition of the subject Electro-Gel is different from the predicates. See**

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also the Device Description section above and Biocompatibility section below.

- **FDA has recently released DRAFT guidance for Electroconductive Media** (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199256.htm). **This guidance recommends** (in addition to a "written description of all ingredients and concentrations," "identification of the pH in the gel formulation" and biocompatibility testing, as referenced above) **that sponsors "evaluate and document the electroconductive medium's...electrical performance and stability to assure that the device performs as intended." Specifically:**
  - The electroconductive medium should be effective in conducting electrical current across the electrode-skin interface. We recommend that you perform impedance testing to assure that the electroconductive medium has conductive properties that are appropriate for the device's intended use.
  - Electroconductive media should be stable and resist physical and chemical breakdown as a result of conducting electrical current and extended periods of storage over a range of environmental conditions. We recommend that you perform testing to establish, for labeling purposes, the device's shelf life and storage conditions.

While I find the above recommendations scientifically valid, because this guidance is still in draft form (i.e., out for public comment, not yet for implementation) and because it concurrently recommends that electro-conductive media be exempt from 510(k) requirements, I must look to the regulatory precedent for guidance about what is appropriate to ask for in this 510(k).

In my limited review of the 57 devices cleared under the 'electroconductive media" regulation, I found a range of requirements for conductive testing. For example:

- ***K883149*: Sponsor provided a summary of results from conductive testing done in an independent lab (page 10 of response to reviewer questions).**
- ***K003924*: Sponsor provided detailed list of product specifications and** "Performance Standards Certification" **stating the device "meets all its requirements including pH, viscosity, conductivity and ingredient mixture."** ***See attached for a copy of this statement.***
- ***K033052*: No documentation of conductive performance or characteristics, and no request for such data from FDA.**

In this 510(k), the sponsor states "The conducting agent of the gel is Sodium Chloride with a ratio of 30 pounds dissolved in 40 gallons of water has been used for more than 30 years" and "During this period there has never been a customer complaint concerning the conductivity of the gel" **(Original submission, page 8 of 34). Since there is no strong regulatory precedent and because the conductive material is similar to that in at least two other non-Electro-Cap cleared 510(k)s, I do not think it necessary to require the sponsor to provide a summary of results from conductive testing. However, I do recommend the sponsor provide specifications and a signed certification that the gel has been tested and meets its design requirements, "including pH, viscosity, conductivity and ingredient mixture." My rationale for this request is as follows:**

- **A lack of "customer complaint concerning the conductivity of the gel" is an inadequate measure of device performance.**
- **OC has noted a lack of conductivity specification and testing in their recent inspection of the sponsor's facilities (see Regulatory History section above an attached e-mail).**

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- **There is precedent for this type of documentation for device performance in at least one (relatively) recent predicate 510(k) (K003924).**

- **I have not yet found testing details in predicate 510(k)s related to stability testing, but all three of the predicates referenced above do provide a shelf life (i.e., expiration) in the device labeling. The current sponsor, Electro-Cap, also provides an expiration date (2 years). In order to provide an expiration date, appropriate design controls would include an assessment of the gel's stability up until this date. While I expect this information to be in the sponsor's device master records** (21 CFR 820.3(j)), **because of the lack of regulatory precedent, I will not ask for the sponsor to provide it in the 510(k).**

For my specific recommended deficiencies, see the Deficiencies section below.

Table 1: Comparison of Electro-Gel to Relevant Predicates

	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
Type of Electrodes Used With	Recording only	Recording	Recording and TENS stimulation electrodes	Recording	Recording only; not for use on "current inducing electrodes"
Ingredients	"commercial lubricating jelly (eg. Lubrafax, K-Y Jelly) with sodium chloride added (approximately one ounce of sodium chloride to 16 ounces of lubricating jelly) to aid in conductivity."	Water Potassium Chloride (conductive) Sodium Chloride (conductive, ionic) "Brij 58" (surfactant) Atlas G-1726 (non-ionic surfactant) Glycerin ("incorporation factor") Calcium carbonate ("calcium compound") 1,2-Propanediol (propylene glycol) (emulsifier) Gelwhite H (Bentonite) (suspension agent) Dowicil 200	Water Cullinix 999 Mixing Salt (sodium chloride) Potassium Bitarttrat Glycerine 99% Phenol Cellosize QP – 100M-H Pigment	Distilled Water Potassium Chloride Calcium Chloride Baking Soda ($NaHCO_3$) Gylcerin Soluble Starch ($C_6H_{10}O_5$) Micananzole ($C_{18},H_{14}C_{14}N_{20}$ HNO_3) Clotrimazole anti-fungal	Water Sodium Chloride (conductive) Aragum T-1998 Powder (viscosity) Potassium Bitartrate (Cream of Tartar) ("improve electrode contact") Glycerin (humectant, preservative, viscosity) Methylparaben (preservative) Propylparaben (preservative)

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	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
		(bacteriostatic agent)			
Ingredient concentrations provided?	No	Yes	Yes	Step-by-step procedure followed to formulate gel – including amounts, timing, temps – provided (Att E)	No
pH of gel formation	*unknown*	6.00 to 6.50	7 +/- 0.5	*unknown*	*unknown*
Duration of Use	*unclear*		1 hour	*unclear*	"…in excess of 8 hours"
Biocomp-atibility Testing provided?	No	**Yes, of final product** – skin irritation. Also provided chemical and toxicity information on individual ingredients (Brij 58, Atlas G 1726, Dowicil 200, Gelwhite H)	**Yes, of final product** –skin irritation, dermal sensitization, cytotoxicity	**Yes, of final product** - irritation, sensitization, dermal sensitization, cytotoxicity,	**No.** Sponsor states the gel is made "from known bio-compatible (food grade) materials" and states their extensive experience with gel is sufficient; "formal testing to ISO 10993-1 would add no value."
Impedance Testing?	None provided	**Yes** – testing done by independent lab; gel impedance is between 1-3 kOhms	No specific protocols provided, but Specifications provided and a "Performance Standards Certification" that states device "meets all its requirements including pH, viscosity, conductivity and ingredient mixture"	None provided	None provided. "The conducting agent:…is Sodium Chloride…has been used for more than 30 years. During this period there has never been a customer complaint concerning the conductivity of the gel."
Shelf life	*unknown*	"Product lot # and expiration date will	6 months	"The expiration date is on the	2 years, "provided the gel is stored in

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	Electro-Cap's Electro-Cap VII System (K780045)	Weaver TEN20 Conductive Paste (K883149)	Mavidon Medical Electrode Jelly (K003924)	Compumedics Quik Gel (K033052)	Electro-Cap's Electro-Gel (subject device)
		be displayed on each container"		bottom of each bottle"	the original container at room temperature with lid tightly closed."
Storage conditions	*unknown*	"Keep lid closed when not in use. Room temperature."	*unknown*	*unknown*	Room temperature; original container; lid tightly closed

VII. Performance Testing

a. Bench and Clinical

Related to performance testing, the sponsor states the following (page 8, yellow highlight added):

> There are no known formal performance standards which apply to the product, but we maintain that the efficacy of the product for its intended use has been demonstrated in the market place, and Electro-Gel's dominant market share. The amount of the 2008 formulated Electro-Gel that has been sold was enough to record more than 10,000,000 EEG's with only one known minor incident reported would also support this claim.
>
> The following comments are also provided as a means of clarification:
>
> **Contact Duration**
> A clinical EEG test will last approximately two hours however brain monitoring during surgery last for several hours. The Electro-Gel is also used in sleep studies for up to 8 hours. There have no reported incidents of adverse skin reaction in any of these situations. Accordingly the contact duration would be in excess of 8 hours.
>
> **Electrical Performance**
> The conducting agent of the gel is Sodium Chloride with a ratio of 30 pounds dissolved in 40 gallons of water has been used for more than 30 years. During this period there has never been a customer complaint concerning the conductivity of the gel.
>
> **Stability**
> Shelf life is 2 years, provided the gel is stored in the original container at room temperature with the lid tightly closed.

The sponsor also submitted an excerpt of pictures from one article in which the Electro-Gel was used on astronauts in space (Attachment A).

The sponsor has submitted no bench or clinical data in this 510(k).

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Reviewer Comment (Original): The sponsor has not adequately addressed performance testing issues for their device. Pictures of astronauts using the gel in space (Attachment A) and assertions that efficacy has been proven in the marketplace because their have been no complaints or major incidents is insufficient.

Please see the Predicate Comparison above for my recommendations as they relate to conductivity and stability testing.

For my specific recommended deficiencies, see the Deficiencies section below.

b. Electrical and EMC Safety

Not applicable. Device does not include any electronic components.

c. Software

Not applicable. Software is not a part of this device or 510(k).

VIII. Sterilization

Not applicable. Device not provided sterile (Original submission, page 7).

IX. Biocompatibility

Related to biocompatibility, the sponsor states the following (page 7, yellow highlight added):

> The Electro-Gel is made from known biocompatible (food grade) materials. The only known instance of bioincompatibility involved one 5 month old pediatric patient in 2011 who suffered minor skin abrasions when the EEG test lasted for 24 hours. The two electrode sites on the back of the scalp, where pressure would have been applied while the child was on its back, were the only 2 of 10 sites affected. It was suggested to our distributor in Japan that the probable cause was the long exposure to the sodium chloride in the gel. The distributor agreed and the customer complaint was closed.
>
> No other reaction to the gel has been recorded during the past 23 years the Electro-Gel has been used.
>
> As such, we maintain that the biocompatibility of the product has been strongly demonstrated and we maintain that formal testing to ISO 10993-1 would add no value.

Reviewer Comment (Original): The sponsor has not adequately addressed biocompatibility issues for their device. Use for "past 23 years" and lack of recorded incidents (except one) is an insufficient replacement to formal testing to ISO 10993-1. This is especially true given the following:

- **All the more recent predicates I reviewed (K883149, K003924, K033052) included biocompatibility testing for skin irritation and the latter (more recent) two of them included tests for sensitization and cytotoxicity.**

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- **Per my informal conversation with Molly Ghosh PhD, it is important to understand how the gel ingredients react together in the final product. Dr. Ghosh helped me draft the deficiency for the sponsor. See attached e-mails.**

For my specific recommended deficiency, see the Deficiencies section below.

X. Labeling

The sponsor provided their proposed labeling in Attachment C of the submission.

The sponsor lists the following important items in their labeling:

- List of ingredients
- Storage instructions
- Storage instructions: "Keep containers tightly closed and at room temperature."
- Expiration: "Expiration data is found on the bottom of the jar"
- "For External Use Only"
- "Use topically on healthy, intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury on the medical condition of the patient."
- "Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions."
- "If rash, redness, itching, swelling, or abnormality appears on skin, wash off immediately. Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites."
- "Avoid eye contact."
- "Do not use with current inducing electrodes."
- "Keep out of the reach of children."

Reviewer Comment (Original): I recommend the labeling add the following:

- **Maximum duration of use**
- **How to remove the gel from the electrode and skin following use**
- **Caution that gel should not be reused.**
- **IFU ("Usage") statement modified to be identical to that stated on the IFU statement.**

For my specific recommended deficiency, see the Deficiencies section below.

XI. Substantial Equivalence Discussion

Not applicable at this time. Recommendation is for AI.

XII. Administrative Requirements

	Yes	No
Indications for Use page (**Prescription**)	X	
Truthful and Accuracy Statement	X	
510(k) Summary or 510(k) Statement	X	

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	Yes	No
Standards Form		X
ClinicalTrials.gov Certification form		X

Reviewer Comment (Original): The sponsor only references quality systems standards in the 510(k), to which I don't believe a Standards Form is required. Though one will be needed if they state conformance to the biocompatibility standard ISO 10993. Additionally, the 510(k) Summary is missing some important information (e.g., other predicates, performance testing summary) and there is no ClinicalTrials.gov certification form.

XIII. Deficiencies

As outlined in the various sections above, this 510(k) has a number of deficiencies. I recommend the following be communicated to the sponsor:

Device Description

1. Your provided device description is incomplete. Please provide additional information regarding the following:
    a. Specific concentrations of ingredients
    b. Maximum duration of use
    c. pH range
    d. Available container sizes.

Device Testing

2. You have not conducted any biocompatibility testing on your device. You justified omission of testing by use of "food grade" materials, reference to the large amount of gel sold and lack of reported incidents, but this is insufficient. We recommend that biocompatibility testing should be conducted on the finished device because biocompatibility of a final device depends not only on the materials used for manufacturing of the device but also on any new chemical entity that could potentially be formed due to interactions of these materials, the processing of the materials, manufacturing method and manufacturing residuals that may be imparted on the final device. Thus, please provide biocompatibility data on your final device. FDA's Blue Book memorandum G95-1 recommends that cytotoxicity, irritation, and sensitization testing be considered for devices with short term skin contact. If identical materials are used in any legally marketed medical devices with same nature and duration of contact, you can identify those devices instead of conducting biocompatibility testing. However, please note that we only consider the materials to be identical if they have the same chemical formulations, same manufacturing processes and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc).

3. You have not adequately addressed performance testing for your device. You justified omission of testing with reference to the large amount of gel sold and lack of reported complaints, but this is insufficient. Isolated case reports and random experience do not constitute valid scientific evidence (21 CFR 860.7(c)(2)). You do not need to submit testing reports, protocols or results in this 510(k) for your device. However, to ensure this testing has been completed, please provide your design specifications for pH, viscosity, conductivity and ingredient mixture and a signed certification

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statement that your final gel has been tested for these specifications and meets all of its requirements.

Labeling

4. You provided labeling in Attachment C of your 510(k). To ensure users know how to safely and effectively use your device, please add the following information to your labeling:
   a. Maximum duration of use
   b. How to remove the gel from the electrode and skin following use
   c. Gel should not be reused.
   d. "Usage" statement modified to be identical to that of your submitted Indications for Use (IFU) statement

Administrative

5. Please revise your 510(k) Summary to meet the requirements outlined in 21 CFR 807.92 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92) and the following specific concerns:
   a. Please provide a more detailed predicate comparison (e.g., predicate comparison table). Please also add more recent and relevant predicates to your list, such as K003924 and K033052.
   b. Please add a summary of your completed device testing, e.g. those related to biocompatibility and conductivity.
   c. Please add the device description information requested in the deficiency above.

6. The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that all original 510(k)s submitted on or after December 26, 2007 (90 days after the enactment date of FDAAA) be accompanied by certification that they are in compliance with the requirements of Title 8 of FDAAA. To meet the requirements of this certification, please submit the following form entitled 'The Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank Form which is available at the following weblink: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf. Please also see CDRH's related guidance at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.

7. FDA encourages you to provide an electronic copy of your submission response. Please refer to our Center web page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm for the latest update of instructions for providing electronic submissions.

XIV. Consults

I informally consulted with Molly Ghosh PhD (DONED/NNDB) about biocompatibility issues. She stated assertion of "food grade" ingredients is an insufficient justification for lack of biocompatibility testing. It is important to understand how the ingredients react together in the final product. She provided me with a sample biocompatibility deficiency which she helped me modify for use with this 510(k) and which I incorporated into my review. See her attached e-mail.

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XV. Contact History

No contact with the sponsor this round of review.

XVI. Original Documents Modified During Review

Not applicable at this time. Recommendation is for AI.

XVII. Recommendation

As outlined above, this submission requires additional information before a final decision can be reached. I recommend this device go ON HOLD until this information is received from the sponsor.

Sara Aguel 7/28/11

Sara Doll Aguel, Biomedical Engineer (07/28/2011)
Neurodiagnostic and Neurotherapeutic Branch
Division of Ophthalmic, Neurological and ENT Devices

Attachments:

- E-mail correspondence with Molly Ghosh PhD about biocompatibility issues (E-mail #1)
- Excerpts from K003924 – Sections 7 (Device Specifications) and 9 (Performance Standards Certification)
- E-mail correspondence with Office of Compliance (E-mail #2)

Yes we do need a 510K Submission for t

RE K111717 - Electrode gel biocom

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Email #1

Aguel, Sara D
From: Aguel, Sara D
Sent: Wednesday, July 27, 2011 9:28 AM
To: Ghosh, Molly
Subject: RE: K111717 - Electrode gel biocompatibility deficiency

Thanks Molly! I'll incorporate all of your changes.

I do have other deficiencies. The letter is on eRoom here:
http://eroom.fda.gov/eRoom/CDRH4/CDRH-ODE-DONED-GuidancesStandardsandReferences/0_24c9d

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
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E-mail: sara.aguel@fda.hhs.gov
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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Ghosh, Molly
Sent: Tuesday, July 26, 2011 11:15 PM
To: Aguel, Sara D
Subject: RE: K111717 - Electrode gel biocompatibility deficiency

Hi Sara,

Thanks for uploading the document.

Please see my edits in red (and comments in green):

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1. You have not conducted any biocompatibility testing on your ~~final~~ device. You justified omission of testing by use of "food grade" materials, reference to the large amount of gel sold and lack of reported incidents, but this is insufficient. We recommend that biocompatibility testing should be conducted on the finished device because biocompatibility of a final device depends not only on the materials used for manufacturing of the device but also on any new chemical entity that could potentially be formed due to interactions of these materials, ~~how they interact together and on~~ the processing of the materials, manufacturing method ~~(including the sterilization process)~~ (*Comment: I deleted the sterilization part to avoid confusion since their device is not sterile*) and manufacturing residuals that may be imparted on the final device. In addition, isolated case reports and random experience do not constitute valid scientific evidence (21 CFR 860.7(c)(2)) *(Comment: I am not sure if you want to refer to 21 CFR 860.7(C)(2) since "reports of significant human experience with a marketed device" is considered a valid scientific evidence in 21 CFR 860.7(c)(2)).* Thus, please provide biocompatibility data on your final device. FDA's Blue Book memorandum G95-1 recommends that cytotoxicity, irritation, and sensitization testing be considered for devices with short term skin contact. ~~In addition, ISO 10993-12 (Biological evaluation of medical devices – Sample preparation and reference materials) recommends that biocompatibility. –~~ If identical materials are used in any legally marketed medical devices with same nature and duration of contact, you can identify those devices instead of conducting biocompatibility testing. However, please note that we only consider the materials to be identical if they have the same chemical formulations, same manufacturing ~~and same sterilization~~ processes and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc).

I don't know when you have to send the AI letter. I will be back on 7/29. I will be at the conference whole day tomorrow. Please call me at my cell 240 252 8358 if you have any questions. Just curious to know if you have any other deficiencies.

Molly

Chandramallika (Molly) Ghosh, Ph.D., DABT
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Center for Devices and Radiological Health
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are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

From: Aguel, Sara D
Sent: Monday, July 25, 2011 9:21 AM
To: Ghosh, Molly
Subject: RE: K111717 - Electrode gel biocompatibility deficiency

Molly,
I just posted the 510k on eRoom here: http://eroom.fda.gov/eRoom/CDRH4/CDRH-ODE-DONED-OngoingActivities/0_24ca5.

Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
US Food and Drug Administration

E-mail: sara.aguel@fda.hhs.gov
Phone #: (301) 796-6494
Fax #: (301) 847-8126
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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Ghosh, Molly
Sent: Sunday, July 24, 2011 9:50 PM
To: Aguel, Sara D
Subject: RE: K111717 - Electrode gel biocompatibility deficiency

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Hi Sara,

Sorry, I couldn't get back to you on Friday. I was in a biocompatibility guidance document meeting whole day. Can I please quickly check the biocompatibility section before we finalize the deficiency. I could not find the file on Image. Do you have an e-copy of the file?

Thanks,
Molly

From: Aguel, Sara D
Sent: Friday, July 22, 2011 3:15 PM
To: Ghosh, Molly
Subject: K111717 - Electrode gel biocompatibility deficiency

Molly,
Please see below for how I changed your sample deficiency for my 510(k). Let me know if you are okay with the wording, given what we have discussed about the device.

Would you also mind sending me a statement that you agree that the justifications the sponsor has provided for *not* doing biocompatibility testing are insufficient (along with your full name and title, per the recent "Informal Communication" SOP)?

Thank you!

Sara

1. You have not conducted any biocompatibility testing on your final device. FDA's Blue Book memorandum G95-1 recommends that cytotoxicity, irritation, and sensitization testing be considered for devices with short term skin contact. In addition, ISO 10993-12 (Biological evaluation of medical devices – Sample preparation and reference materials) recommends that biocompatibility testing should be conducted on the finished device. You justified omission of testing by use of "food grade" materials, reference to the large amount of gel sold and lack of reported incidents, but this is insufficient. Isolated case reports and random experience do not constitute valid scientific evidence (21 CFR 860.7(c)(2)) and because biocompatibility of a final device depends not only on the materials used but also on how they interact together and on the processing of the materials, manufacturing method (including the sterilization process) and manufacturing residuals that may be imparted on the final device. Thus, please provide biocompatibility data on your final device. If identical materials are used in any legally marketed medical devices with same nature and duration of contact, you can identify those devices instead of conducting biocompatibility testing. However, please note that we only consider the materials to be identical if they have the same chemical formulations, same manufacturing and same sterilization processes and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc).

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Sara Doll Aguel
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
US Food and Drug Administration

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Ghosh, Molly
Sent: Thursday, July 21, 2011 3:05 PM
To: Aguel, Sara D
Subject: Deficiency

1. You have not conducted any biocompatibility testing on your final, sterilized device. FDA's Blue Book memorandum G95-1 recommends that cytotoxicity, irritation, and sensitization testing be considered for devices with short term skin contact. In addition, ISO 10993-12 (Biological evaluation of medical devices – Sample preparation and reference materials) recommends that biocompatibility testing should be conducted on the finished, sterile device. You justified omission of testing by stating that all three patient contacting materials in your device have a long history of biocompatible use in medical devices. We disagree with your justification because

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biocompatibility of a final device depends not only on the materials used but also on the processing of the materials, manufacturing method (including the sterilization process) and manufacturing residuals that may be imparted on the final device. Thus, please provide biocompatibility data on your final, sterilized device. If identical materials are used in any legally marketed medical devices with same nature and duration of contact, you can identify those devices instead of conducting biocompatibility testing. However, please note that we only consider the materials to be identical if they have the same chemical formulations, same manufacturing and same sterilization processes and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Excerpt from K003924

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1/7

Section 7
Device Specifications

Attached are the device specifications for the of Mavidon Medical Products product.

(b)(4) device specifications

(b)(4) device specifications

(b)(4) device specifications

(b)(4) device specifications

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6/7

Section 9
Performance Standards

Attached are the Performance Standards for the Mavidon Medical Products product.

73

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Mavidon™
Medical Products
Manufacturing quality products since 1984.

7/7

Performance Standards Certification

I certify, in my capacity as President of Mavidon Medical Products, that the Mavidon Electrode Jelly has been tested for the specifications recorded in the Device Specification section of this submission. The Mavidon Electrode Jelly meets all of its requirements including pH, Viscosity, Conductivity and Ingredient Mixture. Records of each batch are maintained in the corporate files.

Signature

Tim Carroll, President

Date

Toll Free US/Canada (800) 654-0385, 888-913-4311 Fax
(561) 585-2227 Fax (561) 586-6282
2105 7th Ave. No. Lake Worth, FL 33461
e-mail - sales@mavidon.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Email #2

Aguel, Sara D
From: Hoang, Quynh T.
Sent: Wednesday, April 27, 2011 12:39 PM
To: Cathlin, Charles
Cc: Doll, Sara K; Radman, Thomas
Subject: Yes...we do need a 510K Submission for Electro Cap's Electro-Gel

Dear Charles:

We do need a 510(k) submission for the gel, given the changes since the original clearance.

Please ask the inspector to tell the firm that since the original clearance in K780045, the standard for these gels and our review process for them have progressed such that submitting the same information as was submitted in 1978 would not suffice. They should access Device Advice on the FDA website for information on the contents of a 510(k) submission. They should also access these draft guidance documents to have any idea on the type of data that we look for on conductive gel and electrodes.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199256.htm

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199247.htm

I recommend that the inspector contacts Tom Radman for any questions on these guidance documents (just noticed that somehow my name is on these documents).

Thanks.

From: Doll, Sara K
Sent: Monday, April 25, 2011 4:17 PM
To: Cathlin, Charles
Cc: Hoang, Quynh T.
Subject: RE: 510K Submission for Electro Cap's Electro-Gel

The inspector seems to have already asked a lot of tough questions.

The purpose of electro-conductive gel is to help transmit the electrical signal of the brain to the EEG electrode. The ability of the gel to do this is important as the EEG signal is very small and easily affected by electrical noise. Additionally, the risk of the gel includes patient skin irritation. As such, I would think **any** change in the gel formula that *could* affect either the gel's biocompatibility or conductivity (i.e., its safety or efficacy) requires a new 510(k). Changing the conductive element of the gel would certainly fall in that category, as well as changing the viscosity of the gel (if the gel is too runny, it won't stay beneath the electrode and isn't effective). I would also be concerned about adding any ingredients that *could* compromise the gel's biocompatibility.

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Sara K. Doll
Biomedical Engineer/Lead Scientific Reviewer
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
US Food and Drug Administration
E-mail: sara.doll@fda.hhs.gov
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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Cathlin, Charles
Sent: Monday, April 25, 2011 1:24 PM
To: Hoang, Quynh T.; Doll, Sara K
Cc: MacFarland, William C
Subject: FW: 510K Submission for Electro Cap's Electro-Gel

Hi Quyhn and Sarah,

This is a 510k question from CIN-DO, who is currently inspecting the firm, Electro Cap. Looks like the investigator has already identified many major deficiencies. I wanted to verify that the new Electo-Gel formula, as described below, requires a new 510k. Any thoughts?

Thanks

Charles

From: Winters, Cassandra
Sent: Monday, April 25, 2011 11:05 AM
To: Cathlin, Charles
Cc: Connelly, Virginia R
Subject: FW: 510K Submission for Electro Cap's Electro-Gel

Good Morning,

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I spoke with Jennifer Danieley and she stated you would be the correct person to forward this information for review. Please let me know if there is anything else you need.

Thank you

Cassandra L. Winters, SCSO
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237
Ph:513-679-2700 x139
cassandra.winters@fda.hhs.gov

CSO Brigitte Hofmann is currently inspecting Electro-Cap International Inc. (Electro-Cap),1011 W. Lexington Rd, Eaton, OH 45320. FEI: 1626185

Electro-Cap International Inc. manufactures Electro-Gel, a gel for use in EEG procedures (product code GYB). Mr William N. Hardin, President, stated that the gel is part of the Electro-Cap system, with 510K K780045. Electro-Cap manufactures approximately 150 gallons of gel a week. The gel is sold with the firm's electro cap system and independently. The firm stated that the gel is for EEG use, but the firm does not require customers to provide the end use of the device.

According to Mr. Hardin, Electro-Gel has undergone two formula changes. Validation was not performed on either change and the firm does not have design control procedures.

Approximately 10-15 years ago, the firm switched from using Phenol Acid in the gel to using Methylparaben and Propylparaben. Mr. Hardin stated that Dr. Ajaz Hussain from the University of Cincinnati did research through literature to determine this change. Dr. Hussain's research is not documented. Mr. Hardin stated that no testing was done to confirm that the gel was still functioning at the same capacity as the previous formula.

A second change was made to the gel approximately three years ago. The firm was originally using Tragacanth, Powder as a component of the gel. The firm discontinued the use of Tragacanth powder and started using TIC Aragum T-1998. TIC Aragum T-1998 is a mixture of Arabic Gum, Guar Gum, and Xanthan Gum manufactured by TIC Gums, 4609 Richlynn Drive, Belcamp, MD 21017. Mr. Hardin stated that the firm provided a jar of Electro-Gel to TIC. According to Mr. Hardin, TIC stated that Aragum T-1998 is the same viscosity as the Tragacanth powder. Mr. Hardin did not have any documentation of testing.

Mr. Hardin stated that occasionally a customer will request the Electro-Gel to be thicker. The firm uses a hand written formula taped to a jar in the manufacturing room to thicken the gel for customers upon request. There is not a formal procedure for this process and the change in viscosity has not been validated.

I asked Mr. Hardin for the original 510K submission paperwork and testing. The firm did not have any documentation from the 510K submission or validation testing. Mr. Hardin had a copy of the 510K approval letter.

Image 2000 Plus contained documentation from the original 510K submission. This documentation states on page thirty that "The electrode gel is manufactured from commercial lubricating jelly (eg. Lubrafax®, K-Y Jelly®) with sodium chloride added

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(approximately one ounce of sodium chloride to 16 ounces of lubricating jelly) to aid in conductivity." Mr. Hardin stated that salt (sodium chloride) is the conductor in Electro-Gel; however, the ingredients listed on the manufacturing procedure are water, methyparaben, propylparaben, glycerin, tragacanth powder or TIC, potassium bitrate (cream of tarter), and sodium chloride.

In addition to the components being changed in the formula, the specifications have not been identified. Mr. Hardin stated that the firm does not have any specifications for the viscosity of the gel. The firm measures the viscosity of each batch of gel being manufactured, but there are no specifications to check the results of testing the viscosity. Mr. Hardin stated that he is unsure of the specifications for the conductivity of the gel. Mr.. Hardin stated that the employee who manufactures the gel would not know the specifications for the gel conductivity. A former employee tested the conductivity of the gel until March 2011. Mr. Hardin stated that the firm stopped testing gel conductivity after the employee left the firm. Mr. Hardin stated that there was no variation in the gel conductivity for two years prior to ending the conductivity testing. Mr. Hardin stated that the conductivity specifications were on a quality improvement procedure. Mr. Hardin stated that the results of conductivity testing and the conductivity testing procedure are on the former employees computer. Mr. Hardin was not able to furnish this documentation on 04/20/2011.

The new formula of Electro-Gel is different from the original product, and there is no 510K for the new formula of gel currently being manufactured. Would the changes to the product be sufficient grounds for requiring the firm to submit a 510K application for the gel?

Attached are the documents collected thus far, as well as the information from image 2000 plus.
Registration information pp 1-6
Electro-Gel MSDS pp 7-8
Manufacturing Procedure for Gel with Tragacanth pp 9-11
Manufacturing Procedure for Gel with TIC pp 12-14
Formula used to make Gel thicker p 15
Electro-Cap's information regarding their registration status, intended use, and 510K pp16-30
Image 2000 Plus 510K documentation pp 31-60

<< File: electro cap.pdf >>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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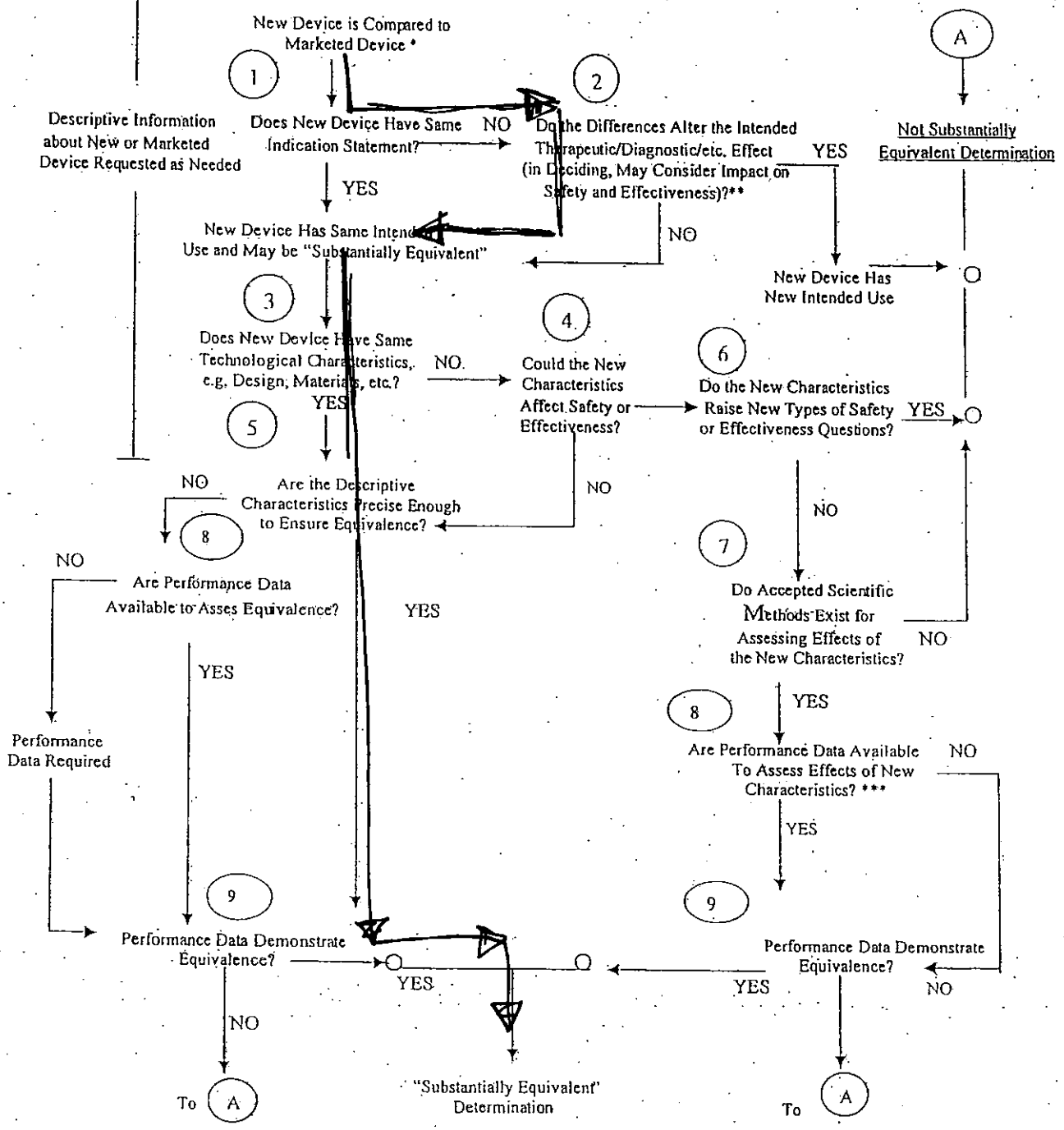
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 10, 2011

ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS

510k Number: K111717

Product: ELECTRO-GEL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Benjamin, Mark D*

From: Microsoft Exchange
'ASWALLOWS@ELECTRO-CAP.COM'
Sent: Thursday, November 10, 2011 12:07 PM
Subject: Relayed: Export.jsp

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'ASWALLOWS@ELECTRO-CAP.COM'

Subject: Export.jsp

Sent by Microsoft Exchange Server 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K111717/S1

Electro-Cap International, Inc.

November 9, 2011

Ms. Sara Doll Aguel
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA CDRH DMC
NOV 10 2011
Received

Re: K111717

Dear Ms. Aguel,

We are writing in response to your letter dated 7/28/11, with regards to our 510(k) filing for Electro-Gel. We are submitting the following information so that the review of our submission may be completed.

1. Device description

(b)(4) device description

[redacted]

K-20

1011 West Lexington Road • P.O. Box 34 • Eaton, OH 45320 • 937-456-7323 • 937-456-7323 • FAX 937-456-7323

Questions? Contact FDA/CDRH/OCE/DD at 240-276-0115 or CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9118.

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2. Device testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following tests: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests. Copies of test reports attached.

Electro-Gel is tested internally for pH, conductivity and viscosity on a regular basis.

3. Device testing

You will find attached our design specifications for pH, viscosity, conductivity and ingredient mixture, along with our certification statement that the gel has been tested and meets these specifications.

4. Labeling

Attachment C has been revised to incorporate the requested information.

5. Administrative

We have revised the 510(k) summary as requested and attached it with this correspondence.

A. We have updated our original predicate device table, and have added a second table which includes the additional predicates as requested.

B. We have added a section for Device Testing in our 510(k) summary.

C. We have added the device description information to the 510 (k) as requested.

6 Form FDA 3674, Certificate of Compliance, under 42 U.S.C. is attached.

7. We have reviewed the information regarding electronic submissions.

We believe we have addressed all the questions in your Additional Information Request for K111717 accurately and completely.

If you have further questions, or need additional information, please do not hesitate to contact us.

Best regards,

Amy Swallows

Amy Swallows
Director of Marketing
Electro-Cap International, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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TOXIKON

ADVANCING YOUR INNOVATION

TOXIKON FINAL GLP REPORT: 11–4075–G1

PRIMARY SKIN IRRITATION TEST – ISO DIRECT CONTACT

Test Article
Electro-Gel

Author
Shirley Lister, B.S., LATG

Final Report Date
October 7, 2011

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Non–Clinical Laboratory Studies

MANAGEMENT OF THE STUDY

Performing Laboratory
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

Sponsor
Electro-Cap International, Incorporated
1011 West Lexington Road
Eaton, OH 45320

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 1: Animal Weights and Clinical Observations
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Appendix I: Classification System for Scoring Skin Reactions
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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STUDY SUMMARY

The test article, Electro-Gel, was evaluated for its potential to produce Primary Skin Irritation after a single topical 4 hour application to the skin of New Zealand White rabbits. No signs of erythema or edema were noted at any observation period. Based on the criteria of the protocol, the test article was considered a negligible irritant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
CLINICAL OBSERVATIONS	09/06/11	09/07/11	09/07/11
RAW DATA	10/07/11	10/07/11	10/07/11
FINAL REPORT	10/07/11	10/07/11	10/07/11

Stacy Hubbard
Stacy Hubbard, M.S.
Quality Assurance

10/07/11
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES

This study meets the technical requirements of the protocol. The study also meets the requirements of the Good Laboratory Practice Regulations, 21 CFR, Part 58, with the exemptions as stated in the Quality Assurance Statement.

Protocol Number:	P10–3594–00A
Study Director:	Shirley Lister, B.S., LATG
Company:	Toxikon Corporation
Signature:	
Date:	10/07/11
Study Supervisor:	Allan Sleger, A.S., LAT

VERIFICATION DATES:
The Study Initiation Date is the date the protocol is signed by the Study Director.

Test Article Receipt:	08/19/11
Project Log Date:	08/19/11
Study Initiation Date:	08/22/11
Technical Initiation:	09/03/11
Technical Completion:	09/06/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

1.0 PURPOSE

The purpose of the study was to evaluate the potential of the test article to produce primary dermal irritation after a single topical exposure to the skin of New Zealand White Rabbits.

2.0 REFERENCES

The study was conducted based upon the following references:

2.1 ISO 10993–10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.

2.2 ISO 10993–12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

2.3 ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

3.0 COMPLIANCE

The study conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Non–Clinical Laboratory Studies.

4.0 IDENTIFICATION OF TEST AND CONTROL ARTICLES

The Sponsor supplied the following information on a test requisition form or other correspondence, wherever applicable (excluding confidential or trade secret information). The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

4.1 Test Article:

Test Article Name: Electro-Gel
CAS/Code #: Not Supplied by Sponsor (N/S)
Lot/Batch #: 7281
Physical State: N/S
Color: N/S
Expiration Date: N/S
Density: N/S
Stability: N/S
Solubility: N/S
pH: N/S
Storage Conditions: Room Temperature
Safety Precautions: Standard Toxikon Laboratory Safety Precautions

4.2 Control Article:
A control article was not used. The untreated skin of each animal served as the control.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Office for Laboratory Animal Welfare (OLAW), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Health Research Extension Act of 1985 (Public Law 99-158 November 20, 1985), Reprinted 1996.

ISO 10993-2, 2006, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirements.

Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

TABLE 1
Animal Weights and Clinical Observations

Test Article: Electro-Gel

Lot/Batch #: 7281

Animal #	Sex	Body Weight (kg)			Signs of Toxicity*
		Day 0 09/03/11	Day 3 09/06/11	Weight Change	
10881	Male	3.59	3.70	0.11	None
10882	Female	3.21	3.31	0.10	None
10883	Male	2.99	3.05	0.06	None

* Summary of Clinical Observations at 24, 48, and 72 h excluding skin reactions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

TABLE 2
Skin Reaction Scores*

Test Article: Electro-Gel

Lot/Batch #: 7281

Test Sites

Animal #	Site 1 / Site 2 09/03/11 60 Minutes**		Site 1 / Site 2 09/04/11 24 Hours		Site 1 / Site 2 09/05/11 48 Hours		Site 1 / Site 2 09/06/11 72 Hours		Total†
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	
10881	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0.0
10882	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0.0
10883	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0.0

Control Sites

Animal #	Site 1 / Site 2 09/03/11 60 Minutes**		Site 1 / Site 2 09/04/11 24 Hours		Site 1 / Site 2 09/05/11 48 Hours		Site 1 / Site 2 09/06/11 72 Hours		Total†
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	
10881	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0.0
10882	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0.0
10883	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0.0

* = Readings taken after bandage removal.
** = 60 minute scores are not included in determining the PII.
† = (Erythema + Edema Scores) / (2 Test Sites × 3 Observation Points).
Primary Irritation Index (PII) = 0.0

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

APPENDIX I
Classification System for Scoring Skin Reactions

Erythema and eschar formation	Value
No erythema	0
Very slight erythema (barely perceptible)	1
Well–defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to slight eschar formation (preventing grading of erythema)	4

Total possible erythema score = 4

Edema formation	
No edema	0
Very slight edema (barely perceptible)	1
Well–defined edema (edges of area well–defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

APPENDIX II
Software Systems

Software	Use
Adobe Acrobat 8 Professional	Document preparation
DocuKnowledge 3.0	Lotus Domino–based document management system used for SOPs
Lotus Domino Rel. 5	Client–server application for sponsor, sample, test codes, and quotation management application databases
MS Office 2007 Small Business Suite	Business software (suite includes Word, Excel, PowerPoint, Outlook, Publisher, Office tools)
Rees CentronSQL System 2.0	Environmental monitoring and metrology system

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

2

TOXIKON

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TOXIKON FINAL GLP REPORT: 11–4075–G2

AGAR DIFFUSION TEST – ISO

Test Article
Electro-Gel

Author
Ryan Ross, B.S.

Final Report Date
September 1, 2011

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Non–Clinical Laboratory Studies

MANAGEMENT OF THE STUDY

Performing Laboratory
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

Sponsor
Electro-Cap International, Incorporated
PO Box 87
Eaton, OH 45320

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Record processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

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Appendix I: Software Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

STUDY SUMMARY

No biological reactivity (Grade 0) was observed in the L929 mammalian cells at 48 hours post exposure to the test article. The observed cellular response obtained from the positive control article (Grade 3) and negative control article (Grade 0) confirmed the suitability of the test system. Based on the criteria of the protocol, the test article, Electro-Gel, is considered non–cytotoxic and meets the requirements of the Agar Diffusion Test defined in ISO 10993–5 guidelines.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
SCORING	08/24/11	08/24/11	08/24/11
RAW DATA	09/01/11	09/01/11	09/01/11
FINAL REPORT	09/01/11	09/01/11	09/01/11

Michael Vandi

Michael Vandi, B.S.
Quality Assurance

9/1/11
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES

This study meets the technical requirements of the protocol. The study also meets the requirements of the Good Laboratory Practice Regulations, 21 CFR, Part 58, with the exemptions as stated in the Quality Assurance Statement.

Protocol Number:	P10–3592–00A
Study Director:	Ryan Ross, B.S.
Company:	Toxikon Corporation
Signature:	Ryan Ross
Date:	9/1/11
Study Supervisor:	Ryan Ross, B.S.

VERIFICATION DATES:
The Study Initiation Date is the date the protocol is signed by the Study Director.

Test Article Receipt:	08/19/11
Project Log Date:	08/19/11
Study Initiation Date:	08/22/11
Technical Initiation:	08/22/11
Technical Completion:	08/25/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

1.0 PURPOSE

The purpose of the study was to determine the biological reactivity of a mammalian monolayer cell culture (L929) in response to the test article. The study design was suitable for solid test articles in a variety of shapes (e.g., elastomeric closures, etc.), liquid test articles or extracts. The agar layer protects the cells from mechanical damage while allowing the diffusion of leachable chemicals from the test article.

2.0 REFERENCES

The study was based upon the following references:

2.1 ISO 10993–5, 2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity.

2.2 ISO 10993–12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

2.3 ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

3.0 COMPLIANCE

The study conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Non–Clinical Laboratory Studies.

4.0 IDENTIFICATION OF TEST AND CONTROL ARTICLES

The Sponsor supplied the following information on a test requisition form or other correspondence, wherever applicable (excluding confidential or trade secret information). The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

4.1 Test Article:

Test Article Name: Electro–Gel
CAS/Code #: Not Supplied by Sponsor (N/S)
Lot/Batch #: 7281, 7179, 7061
Physical State: N/S
Color: N/S
Expiration Date: N/S
Density: N/S
Stability: N/S
Solubility: N/S
pH: N/S
Storage Conditions: Room Temperature
Safety Precautions: Standard Toxikon Laboratory Safety Precautions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Record processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

4.2 Control Articles (Toxikon Supplied):

4.2.1 Negative Control Article Name: Negative Control High Density Polyethylene (Negative Control Plastic)
Toxikon QC #: CSC–04–05–009–CC
Physical State: Solid
Color: White
Storage Conditions: Room Temperature
Safety Precautions: Standard Laboratory Safety Precautions

4.2.2 Positive Control Article Name: Buna–N–Rubber
Toxikon QC #: CSC–03–07–005–CC
Physical State: Solid
Color: Black
Stability: Stable at Room Temperature
Storage Conditions: Room Temperature
Safety Precautions: Standard Laboratory Safety Precautions

5.0 IDENTIFICATION OF TEST SYSTEM

Mouse fibroblast L929 cells are classically used for cytotoxicity studies. The cell line was obtained from the American Type Tissue Collection (ATCC), Manassas, Virginia.

6.0 JUSTIFICATION OF TEST SYSTEM AND ROUTE OF ADMINISTRATION

6.1 Historically, mouse fibroblast L929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to leachable cytotoxic articles.

6.2 The test article was administered *in vitro*, directly to the test system. This was the optimal route of administration available in the test system as recommended by the ISO 10993–5 guidelines.

7.0 EXPERIMENTAL DESIGN AND DOSAGE

7.1 Preparation of Test and Control Articles:

7.1.1 The test article (100 mg) was placed on the Agar measuring approximately 100 mm^2.

7.1.2 The positive control article (Buna–N–Rubber) and negative control article (Negative Control Plastic) were similarly prepared.

7.2 Pre–Dose Procedure:

Cell Culture Preparation:
Cultures of L929 cells were initiated in Serum–Supplemented (Complete) Minimal Essential Medium (MEM) supplemented with 10% fetal bovine serum and incubated at 37 ± 1 °C in a humidified atmosphere containing 5 ± 1% carbon dioxide (CO_2). Cultures that had grown to

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Record processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

approximate confluence at the end of the log phase of the growth curve were used in the assay. The liquid medium was replaced with a serum–supplemented medium/agar mixture that was stained with a vital dye, neutral red, prior to testing (final concentration of agar = 1%). The culture was protected from light for the duration of the assay to prevent cell damage elicited by photo–activation of the stain.

7.3 Dose Administration:

7.3.1 The test and control articles were applied directly to the surface of the agar, so that approximately one–tenth of the cell layer surface was covered.

7.3.2 The test was performed in triplicate.

7.4 Post–Dose Procedure:

7.4.1 Incubation:
All plates were incubated for 48 ± 2 hours at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% CO_2.

7.4.2 The extent of decolorization of the cells stained with neutral red was evaluated at 0, 24, and 48 hours.

8.0 EVALUATION CRITERIA

8.1 The response of the cell monolayer is evaluated under a microscope for cytotoxicity. The zone of biological reactivity (cellular degeneration and malformation) under and around the test and control articles is measured and rated on a scale of 0 to 4. The test system is considered suitable if no signs of cellular reactivity (Grade 0) are noted for the negative control article and the positive control article shows greater than a Mild reactivity (Grade 2). The test article meets the requirements of the test if none of the cultures treated with the test article shows greater than a Mild reactivity (Grade 2). If the suitability of the system had not been confirmed, the test would have been repeated.

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to the area under the specimen
3	Moderate	Zone extends up to 1.0 cm beyond specimen
4	Severe	Zone extends greater than 1.0 cm beyond the specimen

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

8.2 The study and its design employ methodology to minimize uncertainty of measurement and control of bias for data collection and analysis.

9.0 RESULTS

REACTIVITY GRADES

Date	Time	Dish	Test Article		Controls			
					Positive		Negative	
			Zone Size (cm)	Grade	Zone Size (cm)	Grade	Zone Size (cm)	Grade
08/23/11	0 Hours*	A	0.0	0	0.0	0	0.0	0
		B	0.0	0	0.0	0	0.0	0
		C	0.0	0	0.0	0	0.0	0
08/24/11	24 Hours	A	0.0	0	0.5	3	0.0	0
		B	0.0	0	0.5	3	0.0	0
		C	0.0	0	0.5	3	0.0	0
08/25/11	48 Hours	A	0.0	0	0.7	3	0.0	0
		B	0.0	0	0.7	3	0.0	0
		C	0.0	0	0.7	3	0.0	0

* 0 Hours = Pre–dose

10.0 CONCLUSION

No biological reactivity (Grade 0) was observed in the L929 mammalian cells at 48 hours post exposure to the test article. The observed cellular response obtained from the positive control article (Grade 3) and negative control article (Grade 0) confirmed the suitability of the test system. Based on the criteria of the protocol, the test article, Electro-Gel, is considered non–cytotoxic and meets the requirements of the Agar Diffusion Test defined in ISO 10993–5 guidelines.

11.0 RECORDS

11.1 Original raw data are archived at Toxikon Corporation.

11.2 A copy of the final report and any report amendments is archived at Toxikon Corporation.

11.3 The original final report, and a copy of any protocol amendments or deviations, is forwarded to the Sponsor.

11.4 All used and unused test article shall be disposed of by Toxikon, per Sponsor's request.

12.0 CONFIDENTIALITY AGREEMENT

Per corporate policy, confidentiality shall be maintained in general, and in specific accordance with any relevant agreement specifically executed between Toxikon and the Sponsor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

APPENDIX I
Software Systems

Software	Use
Adobe Acrobat 8 Professional	Document preparation
DocuKnowledge 3.0	Lotus Domino–based document management system used for SOPs
Lotus Domino Rel. 5	Client–server application for sponsor, sample, test codes, and quotation management application databases
MS Office 2007 Small Business Suite	Business software (suite includes Word, Excel, PowerPoint, Outlook, Publisher, Office tools)
Rees CentronSQL System 2.0	Environmental monitoring and metrology system

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

2

TOXIKON

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TOXIKON FINAL GLP REPORT: 11-4075-G3

BUEHLER SENSITIZATION TEST – ISO DIRECT CONTACT

Test Article
Electro-Gel

Author
Christopher Parker, M.S.

Final Report Date
November 8, 2011

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Nonclinical Laboratory Studies

MANAGEMENT OF THE STUDY

Performing Laboratory
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

Sponsor
Electro-Cap International, Incorporated
1011 West Lexington Road
Eaton, OH 45320

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

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Table 1: Preliminary Irritation: Animal Weights and Clinical Observations and Skin Reaction Scores
Table 2: Induction and Challenge: Animal Weights and Clinical Observations
Table 3: Challenge Phase: Skin Examination Data

Appendix I: Classification System for Scoring Skin Reactions
Appendix II: Software Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

STUDY SUMMARY

The test article, Electro-Gel, was evaluated for its potential to produce skin sensitization reactions following topical application to albino guinea pigs. The test article is not considered to be a skin sensitizer since none of the test animals exhibited skin reaction scores at the challenge exposure following an induction phase. No reactions were observed in the negative control group.

Based on the criteria of the protocol and the ISO 10993–10 guidelines, the test article meets the requirements of the test.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

Phase	Inspection Date	Date Reported to Study Director	Date Reported to Management
BODY WEIGHTS	09/14/11	09/14/11	09/14/11
RAW DATA	11/08/11	11/08/11	11/08/11
FINAL REPORT	11/08/11	11/08/11	11/08/11

Stacy Hubbard
Stacy Hubbard, M.S.
Quality Assurance Signature

11/08/11
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES

This study meets the technical requirements of the protocol. The study also meets the requirements of the Good Laboratory Practice Regulations, 21 CFR, Part 58, with the exemptions as stated in the Quality Assurance Statement.

Signature Information	
Protocol Number	P10-3593-00A
Protocol Title	BUEHLER SENSITIZATION TEST – ISO DIRECT CONTACT
Study Director	Christopher Parker, M.S.
Company	Toxikon Corporation

Verification Date(s)
The study initiation day is the date the protocol is signed by the Study Director.

Verification Date(s)	
Test Article Receipt	08/19/11
Project Log	08/19/11
Study Initiation	08/22/11
Study Completion	10/15/11

Christopher Parker, M.S., M.B.A.
Study Director Signature

11/8/11
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

1.0 PURPOSE

The purpose of the study was to evaluate the potential of the test article to produce skin sensitization following topical application to albino guinea pigs.

2.0 REFERENCES

The study was based upon the following references:

2.1 Zhai, H., Wilhem, K–P, and H.I. Maibach, eds. Marzulli and Maibach's Dermatotoxicology. 7th edition Boca Raton: CRC Press, 2007. 443–444, 450–451.

2.2 ISO 10993–10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.

2.3 ISO 10993–12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

2.4 ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

3.0 COMPLIANCE

The study conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies.

4.0 IDENTIFICATION OF TEST AND CONTROL ARTICLES

The Sponsor supplied the following information on a GLP Test Requisition Form or other correspondence, wherever applicable (excluding confidential or trade secret information). The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

4.1 Test Article:

Name	Electro-Gel
CAS/Code Number	Not Supplied by Sponsor
Lot/Batch Number	7281

4.2 Negative Control:
Naïve animals were exposed to the test article or dosing solution for the first time at the challenge application.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

4.3 Positive Control Article (Toxikon Supplied):

Name	Dinitrochlorobenzene (DNCB)
Toxikon QC Number	CSC–06–06–007–VV

5.0 IDENTIFICATION OF TEST SYSTEM

5.1 Animals Used in the Study:

Number and Species: 23 Hartley guinea pigs (*Cavia porcellus*)

Sex: 11 males and 12 females (females were non–pregnant and nulliparous)

Weight/Age Range: 324.2–495.3 grams / 21–67 days old (adult)
weighed to the nearest 0.1 g

Health Status: healthy, not previously used in other experimental procedures

Animal Purchase: Elm Hill Breeding Labs, Inc., Chelmsford, MA.

Animal Identification: ear punch

Acclimation: minimum 5 days, under same conditions as for the actual test

Animal Selection: selected from larger pool and examined to ensure lack of adverse clinical signs

5.2 Animal Care and Maintenance:

Animal Room Target Temperature: 68 ± 5 °F

Animal Room Target Relative Humidity: 30–70%

Air Exchanges per Hour: a minimum of 10 changes per hour

Lights: 12–hour light/dark cycle, full spectrum fluorescent lights

Housing: group housed

Cages: suspended stainless steel

Bedding: Alfa Cobs, Scotts Distributing Inc., Hudson, NH (non–contact)

Animal Rations: Teklad 2041, Guinea Pig Diet, Harlan Laboratories, Madison, WI, *ad libitum*

Water: tap water, *ad libitum*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

The laboratory and animal rooms were maintained as limited–access facilities.

6.0 JUSTIFICATION OF TEST SYSTEM AND ROUTE OF ADMINISTRATION

6.1 Justification of Test System:
Albino guinea pigs were used in this study because they have historically been used in skin sensitization tests and the guidelines have no alternative (non–animal) methods. The number of animals was based on the ISO 10993–10 guidelines.

6.2 Route of Administration:
The test article was applied topically because it was a likely route of human exposure.

7.0 EXPERIMENTAL DESIGN AND DOSAGE

7.1 Preparation of Test and Control Articles:
The test and control articles were applied directly to the skin.

7.2 Pre–Dose Procedure:

7.2.1 Animals selected for the study were examined to ensure their skin was free from irritation, trauma, and disease.

7.2.2 Before each application of the test or control article the animals were clipped and shaved or depilated on the left upper back, in an area of about 3 × 4 cm.

7.2.3 Animals were weighed prior to dosing.

7.3 Dose Administration:

7.3.1 Distribution of Animals:
Test animals were distributed into the following groups:

(1)	Experimental	(5 males / 5 females)
(2)	Negative Controls	(3 males /2 females)
(3)	Positive Controls	(2 males / 3 females)
(4)	Preliminary Irritation	(1 male / 2 females)

7.3.2 Preliminary Irritation Phase:

7.3.2.1 A Preliminary Irritation Study was performed with three (3) previously unexposed animals. This phase was run before the start of the induction phase.

7.3.2.2 The test article was applied (by the closed patch technique described in Section 7.3.3.1) to the skin for 6 hours. The concentrations run were 100%, 50%, 25%, and 10%, or Sponsor–specified dilutions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

7.3.2.3 The responses were scored 24 and 48 hours after the test article application and the highest non–irritant and minimal irritant concentrations was determined. Skin reactions was scored according to the four point scale described in Appendix I.

7.3.3 Induction Phase:

7.3.3.1 Closed patches for the experimental group were prepared by soaking 2 × 2 cm gauze pads in 0.4 mL of the test article with a patch covering it.

7.3.3.2 The patch was kept in place with occlusive bandaging.

7.3.3.3 The patch was removed after 6 hours of exposure and any residual test article was washed off with water.

7.3.3.4 The test article was applied for three consecutive days a week for three weeks on one side of the animal.

7.3.3.5 Naïve animals, i.e., untreated during the induction phase, served as a negative control group.

7.3.3.6 During the Induction Phase the test article was applied at the highest concentration that caused no more than a slight erythema for induction. As the test article produced no erythema at its highest dose, it was applied full strength at both induction and challenge.

7.3.3.7 During induction, the positive control substance (0.4 mL of 0.1% DNCB in 95% ethanol) was applied. For the challenge, the positive controls were exposed to 0.05% DNCB in 95% ethanol.

7.3.4 Challenge Application:

7.3.4.1 Fourteen days (± 1 day) after the last induction application, a 4 × 3 cm virgin skin site was shaved on the backs of the experimental and control animals.

7.3.4.2 The challenge test was performed on freshly clipped skin sites in the same way as the 6 hour closed patch test of the induction phase (see Section 7.3.3.1). One virgin site was prepared per animal. The negative control animals were exposed to the test article for the first time at the challenge phase.

7.3.4.3 At 24 ± 2 hours after removal of the challenge dose, the area of the challenge was marked and the whole back was shaved. At least two hours after shaving, the test site was scored. Skin reactions were scored according to the four–point scale described in Appendix I.

7.3.4.4 Reading of the skin area was repeated 48 ± 2 hours after the removal of the challenge patch and the skin reactions were graded.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7.3.4.5 The results were summarized and expressed in the following terms:

Incidence - The number of animals showing a response of 1 or more, at 24 or 48 hours, divided by the number of test animals.

7.4 Post–Dose Procedure:

7.4.1 Animals were weighed at the end of the observation period.

7.4.2 Animals were sacrificed by carbon dioxide inhalation.

7.4.3 All animals survived the duration of the study.

7.4.4 No therapeutic agents were used in any phase of the study.

8.0 EVALUATION CRITERIA

8.1 Evaluation of Data:
Grades of 1 or greater in the test group indicate sensitization. If grades of 1 or greater are noted in control animals, then the skin reactions of test animals, which exceed the most severe control reaction, are presumed to be due to sensitization. The test article is graded according to the frequency of positive responses seen at the Challenge Phase in test and control animals.

8.2 A sensitizer is a test article in which a positive response is observed in at least 15% of the test animals.

8.3 Control of Bias Statement:
The study and its design employ methodology to minimize uncertainty of measurement and control of bias for data collection and analysis, which includes but is not limited to concurrent control data, blanks, and replicates.

9.0 RESULTS

9.1 Preliminary Irritation Trial (Table 1):
Irritation (skin reaction scores) was absent from all the animals.

9.2 Body Weights (Tables 1 and 2):
All animals gained weight during the course of the study.

9.3 Clinical Observations (Tables 1 and 2):
No overt signs of toxicity were evident in any of the animals during the course of the study.

9.4 Challenge Phase (Table 3):
No skin reaction scores were observed in any of the test animals. No skin reaction scores were evident in the negative control group.

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The incidence of the responses post–challenge were calculated to be:

	Test Article		Negative Control		Positive Control	
	24 hours	48 hours	24 hours	48 hours	24 hours	48 hours
Incidence	0/10 = 0%	0/10 = 0%	0/5 = 0%	0/5 = 0%	5/5 = 100%	5/5 = 100%

10.0 CONCLUSION

The test article, Electro-Gel, was evaluated for its potential to produce skin sensitization reactions following topical application to albino guinea pigs. The test article is not considered to be a skin sensitizer since none of the test animals exhibited skin reaction scores at the challenge exposure following an induction phase. No reactions were observed in the negative control group.

Based on the criteria of the protocol and the ISO 10993–10 guidelines, the test article meets the requirements of the test.

11.0 RECORDS

11.1 Original raw data are archived at Toxikon Corporation.

11.2 A copy of the final report and any report amendments is archived at Toxikon Corporation.

11.3 The original final report and a copy of any protocol amendments or deviations is forwarded to the Sponsor.

11.4 All used and unused test article shall be disposed of by Toxikon, per Sponsor's request.

12.0 CONFIDENTIALITY AGREEMENT

Per corporate policy, confidentiality shall be maintained in general, and in specific accordance with any relevant agreement specifically executed between Toxikon and the Sponsor.

13.0 ANIMAL WELFARE STATEMENT

The Sponsor assured that, to the best of their knowledge, this study did not unnecessarily duplicate previous testing and that there were no non–animal alternatives acceptable for the evaluation of this test article as defined by the protocol.

No evidence of pain and distress was reported to the Veterinarian and/or Study Director.

Toxikon strictly adhered to the following standards in maintaining the animal care and use program:

United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, 9 CFR Ch. 1 (1/1/95 edition), Subchapter A–Animal Welfare.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

"Guide for the Care and Use of Laboratory Animals," National Research Council, 2011. (NIH).

Office for Laboratory Animal Welfare (OLAW), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Health Research Extension Act of 1985 (Public Law 99–158 November 20, 1985), Reprinted 1996.

ISO 10993–2, 2006, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirements.

Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International.

14.0 UNFORESEEN CIRCUMSTANCES

Any unforeseen circumstances were documented in the raw data. However, no unforeseen circumstances that affected the integrity of the study were noted.

15.0 PROTOCOL AMENDMENTS/DEVIATIONS

There were no protocol amendments or deviations. No changes to the protocol were required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

TABLE 1
Preliminary Irritation:
Animal Weights and Clinical Observations and Skin Reaction Scores

Test Article: Electro-Gel

Lot/Batch #: 7281

Animal Weights and Clinical Observations

Animal #	Sex	Body Weight (g)			Signs of Toxicity*
		Day 0 09/13/11	48 hour 09/15/11	Weight Change	
21	Male	331.5	342.9	11.4	None
22	Female	380.9	395.6	14.7	None
23	Female	495.3	502.1	6.8	None

* Summary of Clinical Observations, Day 0 through 48 hour.

Skin Reaction Scores**

Animal #	Sex	24 hour 09/14/11	48 hour 09/15/11
21	Male	0	0
22	Female	0	0
23	Female	0	0

** Skin Reaction Scores at 24 and 48 hours after test article application.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

TABLE 2
Induction and Challenge Phase:
Animal Weights and Clinical Observations

Test Article: Electro-Gel

Lot/Batch #: 7281

Group	Animal #	Sex	Dose	Body Weight (g)			Signs of Toxicity*
				Day 0 09/14/11	Day 31 10/15/11	Weight Change	
Test Article	1	Male	0.4 mL	346.9	479.3	132.4	None
	2	Male	0.4 mL	391.2	523.8	132.6	None
	3	Male	0.4 mL	387.2	501.3	114.1	None
	4	Male	0.4 mL	429.8	526.8	97.0	None
	5	Male	0.4 mL	401.3	559.6	158.3	None
	6	Female	0.4 mL	337.4	448.3	110.9	None
	7	Female	0.4 mL	381.2	513.8	132.6	None
	8	Female	0.4 mL	390.7	502.9	112.2	None
	9	Female	0.4 mL	341.0	459.1	118.1	None
	10	Female	0.4 mL	376.5	500.3	123.8	None
Negative Control	11	Male	0.4 mL	382.4	491.3	108.9	None
	12	Male	0.4 mL	376.9	509.8	132.9	None
	13	Male	0.4 mL	422.8	536.8	114.0	None
	14	Female	0.4 mL	406.7	543.1	136.4	None
	15	Female	0.4 mL	391.1	519.6	128.5	None
Positive Control	16	Male	0.4 mL	386.4	488.2	101.8	None
	17	Male	0.4 mL	397.1	533.9	136.8	None
	18	Female	0.4 mL	426.3	592.3	166.0	None
	19	Female	0.4 mL	324.2	466.8	142.6	None
	20	Female	0.4 mL	357.9	473.1	115.2	None

* Summary of clinical observations, Day 0 through Day 31, excluding skin reaction scores.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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TABLE 3
Challenge Phase:
Skin Examination Data

Test Article: Electro-Gel

Lot/Batch #: 7281

Animal #	Day 30 10/14/11	Day 31 10/15/11
Test Article (Skin Reaction Scores)		
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
Negative Control (Skin Reaction Scores)		
11	0	0
12	0	0
13	0	0
14	0	0
15	0	0
Positive Control (Skin Reaction Scores)		
16	2	1
17	2	2
18	1	1
19	3	2
20	2	2

Test Article
Combined Incidence = 0%

Negative Control
Combined Incidence = 0%

Positive Control
Combined Incidence = 100%

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

APPENDIX I
Classification System for Scoring Skin Reactions

Patch Test Reaction	Grade Scale
No Visible Reaction	0
Discrete or Patchy Erythema	1
Moderate and Confluent Erythema	2
Intense Erythema and Swelling	3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

APPENDIX II
Software Systems

Software	Use	Publisher/Vendor	Location
Adobe Acrobat 8 Professional	Document preparation	Adobe Systems, Inc.	San José, CA
DocuKnowledge 3.0	Lotus Domino-based document management system used for SOPs	Prelude Computer Solutions	Parsippany, NJ
Lotus Domino Rel. 5	Client-server application for Sponsor, sample, test codes, and quotation management application databases	IBM Corporation	Armonk, NY
MS Office 2007 Small Business Suite	Business software (suite includes Word, Excel, PowerPoint, Outlook, Publisher, Office tools)	Microsoft Corporation	Redmond, WA
Rees CentronSQL System 2.0	Environmental monitoring and metrology system	Rees Scientific	Trenton, NJ

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

eci

ELECTRO-CAP INTERNATIONAL, INC
1011 W. Lexington Rd., Eaton, OH, 45320, USA
TEL: 937 456-6099 FAX: 937 456-7323 email: eci@electro-cap.co

ELECTRO-GEL CERTIFICATION

The current (after July 2008) formula of Electro-Gel has been, and is, tested for viscosity, pH, and conductivity. Electro-Gel meets all of the requirements listed below. These requirements are in accordance with the design specifications for this product.

	Acceptable Range
Viscosity:	575 to 615 cp
Conductivity:	0.5 kΩ or less
pH:	3 – 7 pH
Ingredients Mixture:	Manufacturing Procedure Attached

Amy Swallows 8/11/11
Amy Swallows
Electro-Cap International, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

SECTION E9

MANUFACTURING PROCEDURE

GEL

(b)(4) device description

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

(b)(4) device description

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

(b)(4) device description

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

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Attachment C

Device Labeling

Electro-Gel A0001 5/11

DIRECTIONS FOR USE AND CAUTIONARY STATEMENT

REF: 16 oz (473ml) 32 oz (946ml) 128 oz (3784ml)

ECI Electro-Gel contains Water, Sodium Chloride, Aragum T-1998 (Gum Acacia, Guar Gum, Xanthan Gum), Potassium Bitartrate (Cream of Tartar), Glycerin, Methylparaben and Propylparaben.

USAGE

For use with non-disposable neurodiagnostic surface electrodes during EEG exams, evoked potential procedures, and brainmapping. For External Use Only.

APPLICATION

Do not use too much gel. The size of the area of gel becomes the effective size of the electrode. This can reduce inter-electrode distances and compromise the exam.

Place a small amount of gel into a clean container. Fill the blunt tip syringe, and inject the gel into each of the recording electrodes. Do not fill the syringe directly from the jar of gel.

If there is no hair at the electrode site, place a sponge disk around the electrode.

When finished recording, gel may be removed from the scalp with mild soap and warm water, and from the cap and electrodes with Ivory© liquid detergent and warm water.

CAUTIONS

Use topically on healthy, intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury on the medical condition of the patient.

Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions. If rash, redness, itching, swelling, or abnormality appears on skin, wash off immediately.

Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites.

Avoid eye contact. May cause mild transient irritation. Wash eyes with appropriate 0.9% saline solution, commercial eye wash solution or water to flush out residual particles. Avoid rubbing eyes.

Patients' tolerance for topical applications to the skin varies widely. Some patients poorly tolerate conductive media and salts. Respond to any complaint that may signal product intolerance.

It is not recommended that the gel be left in place for longer than eight hours for any single recording session.

Do not use with current inducing electrodes.

SAFETY AND HANDLING

The gel is essentially non-toxic, however ingestion could result in nausea, vomiting and/or diarrhea. Drink 1 to 2 glasses of water if ingested.

Electro-Gel is not to be reused.

May be disposed of without special handling. Shelf life is 2 years if stored properly, i.e. kept with containers tightly closed and at room temperature. Expiration date is found on the bottom of the jar.

Keep out of the reach of children.

℞ ONLY

Electro-Cap International, Inc.
1011 W. Lexington Rd.
Eaton, OH 45320 USA
937 456-6099

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

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510K summary

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact:	Amy Swallows
Phone:	937-456-6099
Fax:	937-456-7323
Summary Date:	June 15, 2011 (Revised November 9, 2011)
Trade Name:	Electro-Gel
Common Name:	Electrode Gel
Classification Name:	Media, Electroconductive

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Electro-Gel is an off white color, water-miscible conductive gel consisting of Sodium Chloride as the conductor combined with thickening agents, emulsifiers, humectants and preservatives all in an aqueous solvent. The pH range is 3 - 7 pH. It is available in the following jar sizes: 16 ounce, 32 ounce and 128 ounce.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Technological Characteristics

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, conductivity and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.		K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Table 4.0. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.		K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request 2011-2517, Released by CDRH on 05-02-2012

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
ELECTRO-CAP INTERNATIONAL, INC.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
JUNE 15, 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
1011 W. LEXINGTON ROAD
EATON, OH 45320

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 937-456-6099
(Fax) 937-456-7323

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

ELECTRO-GEL

ELECTRODE GEL

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Amy B Swallows

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) AMY B. SWALLOWS
(Title) DIRECTOR OF MARKETING

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
1011 W. LEXINGTON ROAD
EATON, OH 45320

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 937-456-6099
(Fax) 947-456-7323

15. DATE OF CERTIFICATION
NOV. 09, 2011

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 20, 2011

ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS

510k Number: K111717

Product: ELECTRO-GEL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Grayson, Giovanna *

From: Microsoft Outlook
To: 'aswallows@electro-cap.com'
Sent: Tuesday, December 20, 2011 2:07 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'aswallows@electro-cap.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Tuesday, December 20, 2011 2:07 PM
To: 'aswallows@electro-cap.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 20, 2011
SWALLOWS
B
AMY
ELECTRO-CAP INTL., INC.
1011 WEST LEXINGTON RD.
EATON, OHIO 45320
ATTN: AMY B. SWALLOWS
510k Number: K111717

Product: ELECTRO-GEL
The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510 (k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Sincerely,

510(k) Staff

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Electro-Cap International, Inc.

K111717 | 32

December 19, 2011

Mr. John Grimes
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA/CDRH/DCC
DEC 20 2011
RECEIVED K44

RE: Additional Information Requested for K111717

Dear Mr. Grimes,

We are writing In response to the letter we received dated 12/16/11 referenced above. We are submitting the following information so that our review may be completed:

1. We are revising the acceptable ph range of Electro-Gel to 4-6. We are enclosing the revised 510(k) Summary, the manufacturing procedures, and the Electro-Gel Certification reflecting this change.

2. We have revised our Device Description in the 510(k) Summary to include the glycerine that was inadvertently omitted from our previous response. A copy is attached.

3. We have revised our 510(k) Summary and our manufacturing procedures to show that the impedance of Electro-Gel is .5kΩ. Copies are attached. Our attached Electro-Gel certification also reflects this change.

4. We have attached a copy of our revised 510(k) summary, which now includes the specific amounts of solutes used in manufacturing Electro-Gel. Please note that we have retained our original units of measurement. Also, our labeling has been revised to reflect the change in shelf life of Electro-Gel from 2 years to 1 year. We have also specified continual use for no longer than 8 hours.

We hope this information is sufficient. If you find that you need anything further, please do not hesitate to contact us.

Best regards,

Amy Swallows

Amy Swallows
Director of Marketing
Electro-Cap International, Inc.

1011 West Lexington Avenue • P.O. Box 1018 • Dayton, OH 45402-2193 • 937-456-7699 • FAX 937-456-7323
Questions? Contact FDA/CDRH/OCE/DIDT at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

510K summary

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact:	Amy Swallows
Phone:	937-456-6099
Fax:	937-456-7323
Summary Date:	June 15, 2011 (Revised December 19, 2011)
Trade Name:	Electro-Gel
Common Name:	Electrode Gel
Classification Name:	Media, Electroconductive
Regulation Number:	21 CFR 882.1275
Product Code:	GYB

Predicate Device(s):

510(k) Number: K780045
Manufacture: Electro-Cap International, Inc.
Trade Name: Electro-Gel

510(k) Number: K883149
Manufacture: Weaver and Company
Trade Name: TEN20 Conductive Paste

510(k) Number: K003924
Manufacture: Mavidon
Trade Name: Mavidon Electrode Jelly

510(k) Number: K033052
Manufacture: Compumedics USA, Ltd.
Trade Name: QuikGel

1.0 Description of Device

Electro-Gel is the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to the EEG or computer equipment. Electro-Gel is for use with external electrodes only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

(b)(4) device description

[redacted]

2.0 Intended Use of Device

This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.

3.0 Predicate Comparison

The Electro-Gel has the same technological characteristics as the predicate devices. It is the conductor between the scalp and electrodes and reduces impedance between the electrode and the scalp.

(Please refer to the comparison tables on the following four pages).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Table 4.0 compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates (Prior July 2008) and TEN20 Conductive Paste.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	ELECTRO-GEL Prior July 2008	TEN20 Conductive Paste	Substantial Equivalence Comments
510K No.	K111717	K780045	K883149	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	Use with non-disposable neurodiagnostic electrodes during EEG exams, EP procedures, ENG exams, brainmapping andMSLT procedures	Electro-Gel is used in the same environments and is substantially equivalent to the predicates.
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments as predicates.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Tragacanth, Glycerine	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL*	No OSHA PEL*	No OSHA PEL*	Same as predicates
Preservative	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Methylparaben and Propylparaben	Same as predicates

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Biocompatibility	Test in accordance with ISO 10993		Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	No	Yes	Same as predicates
Irritation	Yes	No	Yes	Same as predicates
Sensitization	Yes	No	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic Excessive exposure to fingers may become chapped and dry	Equivalent to predicates

4.1 Comparison Summary

As shown above in Table 4.0, the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Table 4.0. Compares features and specifications of the current (After July 2008) Electro-Gel under review to the predicates Mavidon Electrode Jelly and Compumedics Quik Gel.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-GEL After July 2008	MAVIDON ELECTRODE JELLY	QUIK GEL	Substantial Equivalence Comments
510K No.	K111717	K003924	K033052	
Indication for Use	Use with external electrodes as the conductor between skin and electrode and to reduce impedance between the electrode surface and the skin	A thixotropic conductive gel for use with silver, gold or tin electrodes.	The Quik Gel is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.	Electro-Gel is used in the same environments and is substantially equivalent to the predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Used in the same clinical environments.
Intended user	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same as predicates
Conductive material	Salt (NaCl)	Salt (NaCl)	Salt (NaCl)	Same as predicates
Thickening agent	Aragum, Glycerine	Hydroxyethyl Cellulose	Glycerine	Equivalent to predicates
Sterilization Method	Provided Non-Sterile	Provided Non-Sterile	Provided Non Sterile	Identical sterilization status
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same as predicates
Preservative	Methylparaben and Propylparaben	Phenol	Anti-fungal Agents	Similar to predicates

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Biocompatibility	Test in accordance with ISO 10993	Yes	Test in accordance with ISO 10993	Same as predicates
Cytotoxicity	Yes	Yes	Yes	Same as predicates
Irritation	Yes	Yes	Yes	Same as predicates
Sensitization	Yes	Yes	Yes	Same as predicates
Characteristics	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Salt Base Non-irritating Non Toxic	Same as predicates

4.1 Comparison Summary

As shown above in Table 4.0 Add., the "July 2008 Electro-Gel brand EEG conductive gel" included in the submission, is identical in all aspects to the predicate "Prior July 2008 Electro-Gel brand EEG conductive gel" except for the thickening agent Aragum, which replaced a like gum, Tragacanth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

4.0 Device Testing

The Electro-Gel has been tested by Toxikon Corporation, FDA/USDA Registered, in compliance with 21CFR, Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies, for the following test: Agar Diffusion Test, ISO 10993-5,-12, Primary Skin Irritation Test-ISO Direct Contact, ISO 10993-10,- 12 and Buehler Sensitization Test, ISO 10993-10, - 12. The Electro-Gel passed all tests.

Electro-Gel is tested internally for pH, impedance and viscosity on a regular basis.

4.0 Conclusions

Based on the results of the non-clinical tests (that demonstrate that the device is as safe, as effective and performs as well as the other legal marketed devices) we conclude that the intended use and technology of the Electro-Gel is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

MANUFACTURING PROCEDURE
ELECTRO-GEL

[redacted]

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Data Information

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

eci

ELECTRO-CAP INTERNATIONAL, INC
1011 W. Lexington Rd., Eaton, OH, 45320, USA
TEL: 937 456-6099 FAX: 937 456-7323 email: eci@electro-cap.co

ELECTRO-GEL CERTIFICATION

The current (after July 2008) formula of Electro-Gel has been, and is, tested for viscosity, pH, and impedance. Electro-Gel meets all of the requirements listed below. These requirements are in accordance with the design specifications for this product.

	Acceptable Range
Viscosity:	575 to 615 cp
Impedance:	0.5 kΩ or less
pH:	4 - 6 pH
Ingredients Mixture:	Manufacturing Procedure Attached

Amy Swallows 12/19/11
Amy Swallows
Electro-Cap International, Inc.

rev. 12/19/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-8537; Released by CDRH on 03-07-2016.

Attachment C

Device Labeling

Electro-Gel A0001 5/11

DIRECTIONS FOR USE AND CAUTIONARY STATEMENT

REF: 16 oz (473ml) 32 oz (946ml) 128 oz (3784ml)

ECI Electro-Gel contains Water, Sodium Chloride, Aragum T-1998 (Gum Acacia, Guar Gum, Xanthan Gum), Potassium Bitartrate (Cream of Tartar), Glycerin, Methylparaben and Propylparaben.

USAGE

For use with non-disposable neurodiagnostic surface electrodes during EEG exams, evoked potential procedures, and brainmapping. For External Use Only.

APPLICATION

Do not use too much gel. The size of the area of gel becomes the effective size of the electrode. This can reduce inter-electrode distances and compromise the exam.

Place a small amount of gel into a clean container. Fill the blunt tip syringe, and inject the gel into each of the recording electrodes. Do not fill the syringe directly from the jar of gel.

If there is no hair at the electrode site, place a sponge disk around the electrode.

When finished recording, gel may be removed from the scalp with mild soap and warm water, and from the cap and electrodes with Ivory© liquid detergent and warm water.

CAUTIONS

Use topically on healthy, intact skin only. Do not use on or near open wounds, bruised or weakened skin due to injury on the medical condition of the patient.

Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions. If rash, redness, itching, swelling, or abnormality appears on skin, wash off immediately.

Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites.

Avoid eye contact. May cause mild transient irritation. Wash eyes with appropriate 0.9% saline solution, commercial eye wash solution or water to flush out residual particles. Avoid rubbing eyes.

Patients' tolerance for topical applications to the skin varies widely. Some patients poorly tolerate conductive media and salts. Respond to any complaint that may signal product intolerance.

It is not recommended that the gel be left in place for longer than eight hours for any single recording session.

Do not use with current inducing electrodes.

SAFETY AND HANDLING

The gel is essentially non-toxic, however ingestion could result in nausea, vomiting and/or diarrhea. Drink 1 to 2 glasses of water if ingested.

Electro-Gel is not to be reused.

May be disposed of without special handling. Shelf life is 1 year if stored properly, i.e. kept with containers tightly closed and at room temperature. Expiration date is found on the bottom of the jar.

Keep out of the reach of children.

℞ ONLY

Electro-Cap International, Inc.
1011 W. Lexington Rd.
Eaton, OH 45320 USA
937 456-6099

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.