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U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K950339 - 108 pages
COMPANY:	KARL STORZ ENDOSCOPY-AMERICA, INC. (KARLSTORENDOAMER)
PRODUCT:	ENDOSCOPE AND/OR ACCESSORIES (KOG)
SUMMARY:	Product: KSEA STEINER ELECTROMECHANIC MORCELLATOR
DATE REQUESTED:	Aug 30, 2016
DATE PRINTED:	Aug 30, 2016
Note:	Printed

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

Karl Storz
Endoscopy America, Inc.

600 Corporate Pointe
Culver City, California
Phone 310 558 [illegible]

SUMMARY OF SAFETY AND EFFECTIVENESS

The Karl Storz Steiner Electromechanic Morcellator and the predicate devices are motorized surgical devices which morcellate and remove tissue from the surgical site. These instruments are designed for use by qualified surgeons during urology endoscopic procedures.

The device comes into contact with the human body for brief periods of time. The body contact material is commonly used in medical devices for a wide range of applications, and has a long history of biocompatibility for human use.

The Karl Storz Steiner Electromechanic Morcellator is substantially equivalent to the predicate devices since the basic features, design, and intended uses are the same. The minor differences in design and dimensions between the Karl Storz Steiner Electromechanic Morcellator and accessories and the predicate devices raise no new issues of safety and effectiveness as these design differences have no effect on the performance, function, or intended use of the devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 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 Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

Karl Storz Endoscopy-America, Inc.
Marika Anderson
Regulatory Affairs Specialist
600 Corporate Pointe
Culver City, CA 90230-7600

Re: K950339
Trade/Device Name: KSEA Steiner Electromechanic Morcellator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated (Date on orig SE ltr): March 27, 1995
Received (Date on orig SE ltr): March 29, 1995

Dear Marika Anderson,

This letter corrects our substantially equivalent letter of April 6, 1995.

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

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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.

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 contact 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. 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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 301-796-8118

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K951104

SEP - 6 1995

SECTION II
SUMMARY AND CERTIFICATION

The Summary of Safety and Effectiveness for the EndoBoot reflects data available and presented at the time the submission was prepared, but, caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Procedure/Product Overview

Endoscopes and surgical/medical instruments are expensive, delicate, and require appropriate storage to ensure the devices function with diagnostic accuracy. The Endoscope Boot is used to assist in the protection of the delicate lens components and other distal tip mechanisms of an endoscope and the delicate components of surgical instruments during transport and storage.

Manufacturing Overview

U.S.E. manufactures and tests the product to performance specifications based on predicate and/or substantially equivalent devices.

U.S.E. manufacturing processes and procedures are based on good manufacturing practices. Quality assurance methods and procedures based on MIL-Q-9858 are utilized to assure conformance to design specifications.

Materials used in the manufacturing process are certified to standards appropriate for their use.

Sterility Testing

The EndoBoot will not be sterilized.

Bibliography

Ravenscroft, M.M. and Swan, C.H.J. Gastrointestinal Endoscopy and Related Procedures: A Handbook for Nurses and Assistants. Baltimore: Williams & Wilkens, 1984.

Berci, George. Endoscopy. New York: Appleton-Century -Crofts 1976.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 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 Center – WO66-G609
Silver Spring, MD 20993-0002

January 15, 2014

Dear Manufacturer:

The product code KOG (Endoscope and/or accessories) under the regulation 876.1500 Endoscope and accessories has been used extensively to include a large variety of medical devices associated with endoscopes. Subsequent to the generation of KOG, additional product codes have been generated that group similar devices into more specific groups. It was decided that the product code KOG would no longer be used and that all endoscopes and/or accessories would use the more specific product codes.

This letter is to notify you that the product code for your device has been changed from KOG to a more specific product code(s) (see the enclosed corrected SE letter). Any other previously assigned product codes remain unchanged.

If you have any questions regarding the contents of this letter, please contact Tuan Nguyen at (301) 796-5174.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 1995

Ms. Marika Anderson
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230-7600

Re: K950339/A
KSEA Steiner Electromechanic
Morcellator
Dated: March 27, 1995
Received: March 29, 1995
Regulatory class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Ms. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

12N 3/31/95 RCN

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

510(K) ROUTE SLIP

510(k) NUMBER K950339 PANEL GU DIVISION DRAER BRANCH HLD3

TRADE NAME KSEA STEINER ELECTROMECHANIC MORCELLATOR

COMMON NAME TISSURE MORCELLATOR

PRODUCT CODE ___

APPLICANT KARL STORZ ENDOSCOPY-AMERICA, INC.
SHORT NAME KARLSTORENDOAMER
CONTACT MARIKA ANDERSON
DIVISION
ADDRESS 600 COROPORATE POINTE
CULVER CITY, CA 902307600
PHONE NO. (310) 558-1500 FAX NO. (310) 410-5527

MANUFACTURER KARL STORZ ENDOSCOPY-AMERICA, REGISTRATION NO. 2020550

DATE ON SUBMISSION 26-JAN-95 DATE DUE TO 510(K) STAFF 12-APR-95

DATE RECEIVED IN ODE 27-JAN-95 DATE DECISION DUE 27-APR-95

DECISION __ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	27-MAR-95	29-MAR-95	12-JUN-95	27-JUN-95	

CORRESPONDENCE	SENT	DUE BACK	
C001	03-MAR-95	02-APR-95	HOLD LETTER

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Russ Pagano

Subject 510(k) NUMBER K950339/S1

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

- [x] Is substantially equivalent to marketed devices.
- [ ] Requires premarket approval. NOT substantially equivalent to marketed devices.
- [ ] Requires more data.
- [ ] Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? [ ] YES [x] NO

Is this device subject to the Tracking Regulation? [ ] YES [x] NO

Was clinical data necessary to support the review of this 510(k)? [ ] YES [x] NO

This 510(k) contains: Truthful and Accurate Statement [ ] Requested [ ] Enclosed N/A
(required for originals received 3-14-95 and after)

- [x] A 510(k) summary OR [ ] A 510(k) statement
- [ ] The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95: [x] No Confidentiality

[ ] Confidentiality for 90 days [ ] Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: KOG FAR 78CFR876.1500 Class II Tier II

Additional Product Code(s) with panel (optional):

REVIEW: Marla Kramer ULOB 4/6/95
(BRANCH CHIEF) (BRANCH CODE) (DATE)

FINAL REVIEW: R Anthony for Lin 4/6/95
(DIVISION DIRECTOR) (DATE)

Revised 3/8/95

3

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

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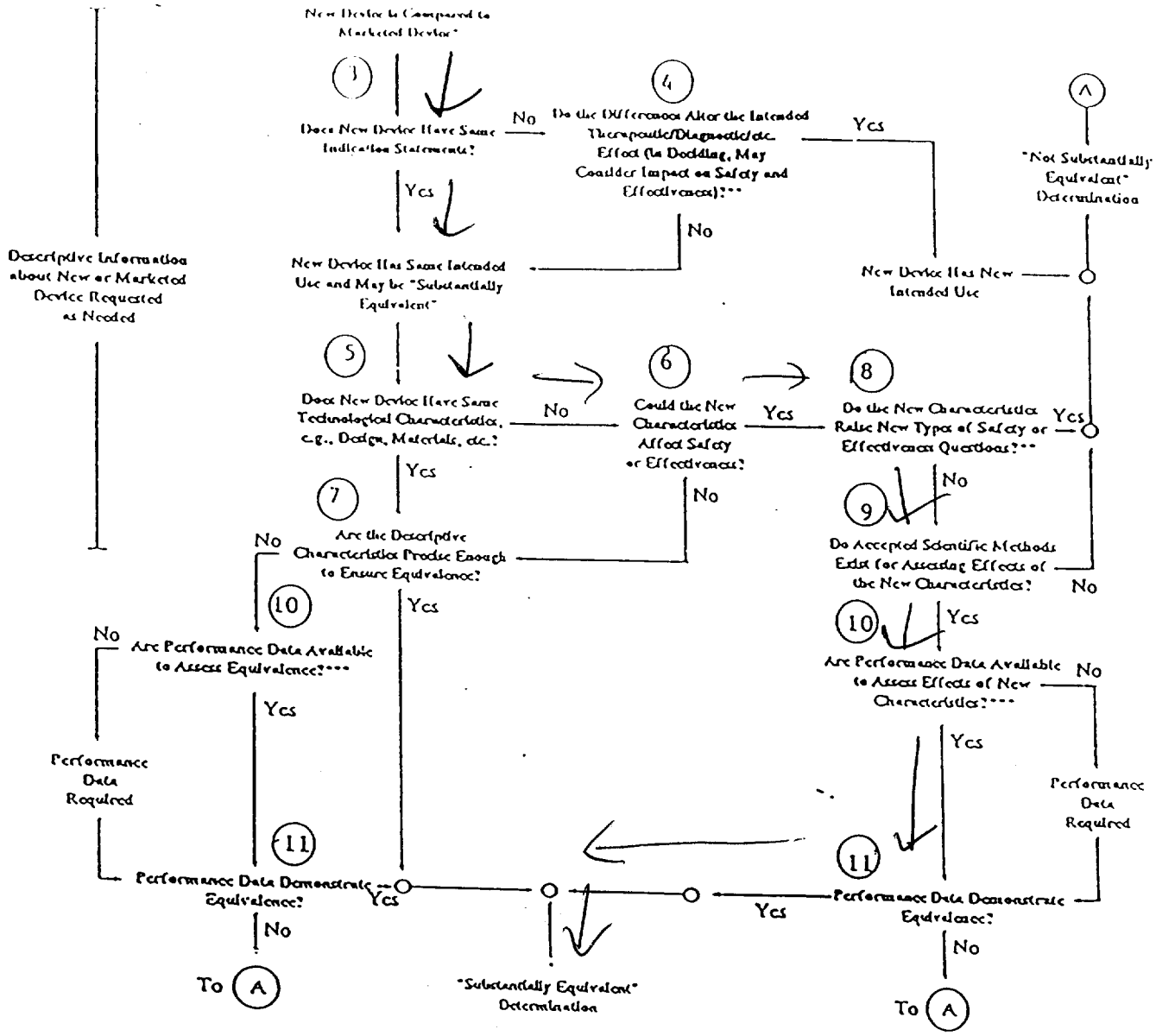
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 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 may be 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 301-796-8118

K 950339 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

REVIEWER: Russ Payne DIVISION/BRANCH: DRAERP/HCPB

TRADE NAME: KSE A Steiner Electromechanic Model COMMON NAME: Morcellator

PRODUCT TO WHICH COMPARED: Cook (K910939), Pyronics (K880150)
(510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?	X		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	X		- IF NO STOP
3. SAME INDICATION STATEMENT?	X		- IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?		X	- IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	X		- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?			- IF NO GO TO 10 - IF YES STOP - SE
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?		X	- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?	X		- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?	X		- IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?	X		SE

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

Memo to the Record

Date: April 5, 1995

From: Russell P. Pagano, Mechanical Engineer
Urology and Lithotripsy Branch, DRAERD (HFZ-472)

Subject: K950339/S1 (Tier II)
KSEA Steiner Electromechanic Morcellator
Karl Storz Endoscopy-America, Inc.

Contact: Marika Anderson
Regulatory Affairs Specialist, KSEA
600 Corporate Pointe
Culver City, Ca. 90230
(310) 558-1500 x331
(310) 410-5519 (Fax)

Karl Storz Endoscopy-America, Inc. (KSEA), has submitted this supplement to K950339 in response to an ODE AI letter of March 3, 1195. The application seeks 510(k) market clearance for KSEA's Steiner Electromechanic Morcellator. The sponsor claims this device is substantially equivalent to devices currently marketed by Cook (K910939), Dyonics (K880150 and K892062), and KSEA's own devices (pre-amendments, K935070, and K940347).

Device Description:

Is the device life supporting or life sustaining?	No
Is the device implanted (short-term or long-term)?	No
Does the device use software?	No
Is the device sterile?	No
Is the device for single use?	No
Is the device for home use?	No
Does the device contain drug or biological products as a component?	No
Is the device a kit?	No

Karl Storz Endoscopy-America, Inc.'s, Electromechanic Morcellator is intended to be used to cut and remove tissue from the body under direct vision open surgical procedures and/or endoscopic procedures including laparoscopic ones. For this application, KSEA is requesting clearance for the device for urological procedures, including nephrectomy. The device had previously been submitted (December 1994) to both the General Surgery (K946213) and Ob/Gyn (K946147) Branches with different procedures listed. General Surgery cleared the device for general surgical use on January 27, 1995, and it is currently under review in the Ob branch. A detailed review of the device can be found in my March 1, 1995 memo. This aforementioned AI letter was generated from concerns outlined in this memo. The firm's responses to these questions are examined below.

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

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ODE Question #1: Please provide bench testing that shows that your device can effectively resect tissue without any indications of wear or breakdown. This testing could consist of resecting animal tissue (e.g., beef kidney) through the device for an appropriate length of time.

(b)(4)

[redacted]

sign of wear or breakdown. The test is very similar to that performed by the Concept Cuto Soft Cutter (k932700), and this response is acceptable.

ODE Question #2: Please provide one of the following: a certification that the device complies with an applicable standard for electromagnetic compatibility, results of testing that demonstrates the device compatibility, or a justification of why you believe neither a certification or testing are necessary.

In their response, KSEA has certified that the device complies with IEC-601-1. This response is acceptable.

ODE Question #3: Since the handle of your device will be in the sterile surgical field, and, thus, should be sterilized, please remove the reference in your instructions for use that states that disinfection is an acceptable end reprocessing procedure for the handle.

In their response, KSEA has removed reference to disinfection for the handle. This response is acceptable.

ODE Question #4: Please either identify what urological procedures would utilize a dextran solution or remove the cleaning statements that relate to dextran from your reprocessing instructions.

In their response, KSEA has removed reference to Dextran solution in the cleaning statements. This response is acceptable.

ODE Question #5: Please state your validation methods for each type of sterilization procedure described in your instructions.

In their response, KSEA states that the sterilization will be validated using the AAMI overkill method with a Sterility Assurance Level (SAL) of 10^{-6}. This response is acceptable.

510(k) Summary:

In accordance with SMDA 1990, KSEA has submitted a 510(k) Summary.

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

Recommendation:

I recommend that this application be considered to be Substantially Equivalent (SE) to predicate devices of this nature, including devices currently marketed by Cook (K910939), Dyonics (K880150 and K892062), and KSEA's own devices (pre-amendments, K935070, and K940347).

Classification:

Endoscopic ~~Electrosurgical Unit and~~ Accessories, ~~FAR~~ KOG - ~~Unit, Electrosurgical,~~ Class II; 78 CFR § 876.~~4300~~ 1500 (procode changed to Endoscopes & Accessories) MCrame

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON THE FLOWCHART (AS NEEDED):

5. Does new device have same technological characteristics?

   No. The new device utilizes a mechanical extraction procedure with the claw forceps, while the predicate devices all utilize a vacuum extraction procedure.

6. Could the new characteristics affect safety and effectiveness?

   Yes. Although all of the devices are designed to morcellate tissue, the design difference (forceps versus vacuum extraction) could affect the safety and effectiveness of the devices since it is a new design.

8. Do the new characteristics raise new type of safety and effectiveness questions?

   No. The ability of the device to safely morcellate tissue is already investigated in any review of these types of devices.

11. Performance data demonstrate equivalence?

   Yes. The bench testing submitted by KSEA (Question 1 above) illustrates that the new device can morcellate tissue at equivalent rates as the predicate devices. Additionally, this morcellation does not cause any new safety issues to arise.

Russell P. Pagano

Concur M. J. Cornelius 4/6/95

MCrame

8

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 30, 1995

KARL STORZ ENDOSCOPY-AMERICA, INC.
600 COROPORATE POINTE
CULVER CITY, CA 90230
ATTN: MARIKA ANDERSON

510(k) Number: K950339
Product: KSEA STEINER ELECTROMECHANIC MORCELLATOR

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 (HFZ-401) 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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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

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Karl Storz
Endoscopy America, Inc.

600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558 1500

Toll Free 800 421 0837
Fax 310 410 5527

K950339/S1

Ref to :
95-032- MA

March 27, 1995

RECEIVED
29 MAR 95 12 57
FDA/CDRH/ODE/DMC

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: K950339 (Karl Storz Steiner Electromechanic Morcellator and Accessories for use in Urology)

Dear Sir or Madam:

Additional information as requested by letter dated March 3, 1995 is provided below.

1. Please provide bench testing that shows that your device can effectively resect tissue without any indications of wear or breakdown. This testing could consist of resecting animal tissue (e.g., beef kidney) through the device for an appropriate length of time.

(b)(4)

[redacted]

2. Please provide one of the following: a certification that the device complies with an applicable standard for electromagnetic compatibility, results of testing that demonstrates the device compatibility, or a justification of why you believe neither a certification or testing are necessary.

KSEA certifies that the Steiner Electromehanic Morcellator complies with IEC-601-1.

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

3. Since the handle of your device will be in the sterile surgical field, and thus, should be sterilized, please remove the reference in your instructions for use that state that disinfection is an acceptable end reprocessing procedure for the morcellator handle.

Reference to disinfection has been removed from the instruction manual. See attachment 1 for revised instruction manual pages.

4. Please identify what urological procedures would utilize a dextran solution or remove the cleaning statements that relate to dextran form your reprocessing instructions.

Reference to dextran has been eliminated from the cleaning statements. Please see attachment 2 for revised cleaning instructions.

5. Please state your validation methods for each type of sterilization procedure described in your instructions.

AAMI overkill method with an SAL of 10^{-6}.

We hope that the enclosed information will enable FDA to clear this application without any further delay. If there are additional questions, please contact me at the following number: 1-800-421-0837, ext. 331.

Sincerely,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

cc: T. Richards
K950339
Chron

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

ATTACHMENT 1

12

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

DRAFT

Changing the cutting knife

Caution: Always pull out the power plug beforehand!

1. Unscrew the black screw cap at the proximal end of the handle.

2. Remove the larger screw cap at the distal end of the handle. The cutting knife can now be pulled out.

3. Insert the new cutting knife. Then reassemble the handle in reverse sequence.

Fuse replacement

Caution: Always pull out the power plug beforehand!

1. Remove the power fuse holder with a screwdriver or other tool.

2. Insert new fuses of the appropriate rating.

3. Replace power fuse holder.

Cleaning and care of the unit

Caution: Always pull out power plug before cleaning.

The instrument surface should be cleaned with a mild cleaning agent or disinfectant. Do not allow any cleaning liquid to get into the instrument.
The morcellator handle and the motor may be steam or gas sterilized.

The connecting cord may be steam or gas sterilized.
Do not disinfect the connecting cord in antiseptic solutions.

Manufacturer's warranty

For one year as of delivery to the end customer we agree to replace the goods free of charge if proof can be provided of faulty materials or faulty workmanship. In doing so we cannot accept to bear the cost of transportation or the risk of shipment. The warranty referred to in § 3 of our Standard conditions of Business shall apply.

Opening the equipment or performance of any repairs or modifications of the equipment by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair or modification during the warranty period shall void all warranty.

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Questions? Contact FDA/CDRH/OCE/DIS at DISTRIBUTION@fda.hhs.gov or 301-796-8118

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DRAFT

Changing the cutting knife

Caution: Always pull out the power plug beforehand!

1. Unscrew the black screw cap at the proximal end of the handle.
2. Remove the larger screw cap at the distal end of the handle. The cutting knife can now be pulled out.
3. Insert the new cutting knife. Then reassemble the handle in reverse sequence.

Fuse replacement

Caution: Always pull out the power plug beforehand!

1. Remove the power fuse holder with a screwdriver or other tool.
2. Insert new fuses of the appropriate rating.
3. Replace power fuse holder.

Cleaning and care of the unit

Caution: Always pull out power plug before cleaning.

The instrument surface should be cleaned with a mild cleaning agent or disinfectant. Do not allow any cleaning liquid to get into the instrument.

The morcellator handle and the motor may be steam or gas sterilized, or disinfected in cold antiseptic solutions.

The connecting cord may be steam or gas sterilized.

Do not disinfect the connecting cord in antiseptic solutions.

Manufacturer's warranty

For one year as of delivery to the end customer we agree to replace the goods free of charge if proof can be provided of faulty materials or faulty workmanship. In doing so we cannot accept to bear the cost of transportation or the risk of shipment. The warranty referred to in § 3 of our Standard conditions of Business shall apply.

Opening the equipment or performance of any repairs or modifications of the equipment by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair or modification during the warranty period shall void all warranty.

Questions? Contact FDA/CDRH/OGE/DIS at CDRH-Industry@fda.hhs.gov or 301-796-5708

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ATTACHMENT 2

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

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CLEANING AND STERILIZATION INFORMATION FOR KARL STORZ ENDOSCOPIC INSTRUMENTS

I. CLEANING

Proper care and maintenance of surgical instruments requires complete disassembly and meticulous mechanical cleaning. Careful attention to detail will prolong the useful life of instruments and protect patients from cross-infection.

Prior to any sterilization procedure, all organic matter, blood and irrigation fluid must be removed. Use a liquid detergent with a neutral pH that is designed for use with surgical instruments. Powdered soaps may leave deposits that can cause corrosion or interfere with moving parts. Distilled or demineralized water is recommended for cleaning, as saline or mineral deposits in tap water may pit or corrode the instruments.

When cleaning, avoid using abrasive materials. Use soft cloths or scrub brushes, toothbrushes and cotton tip applicators to remove residual organic matter, blood or irrigation fluid. Proper contact of the sterilization medium to the instruments will occur only if the instruments are clean. Steam will penetrate residual organic matter, but the residue that will be left after sterilization may subsequently affect operation of the instruments.

Thorough rinsing of instruments with distilled, demineralized or tap water is essential. Dry thoroughly. Cleaning pistols which attach to water or air are useful time-saving tools for both rinsing and drying.

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

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II. LUBRICATION

All moving parts should be lubricated to prevent "freezing" of stopcocks, forcep jaws and other moving parts.

Prior to sterilization, some instruments can be partially reassembled. However, tight locking mechanisms (e.g., washer assemblers, trap door valves) and channel caps should not be reassembled, since this might interfere with sterilization

III. STERILIZATION

In order to achieve the desired standard assurance level (SAL) of 10^{-6}, we recommend steam and EtO sterilization methods. Sterilize as often as needed and/or desired. **Do not sterilize or disinfect the connecting cord in antiseptic solutions**. Discard the device if it is cracked, bent, tarnished or otherwise damaged.

A. Steam Sterilization

(b)(4)

[redacted]

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marika Anderson
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230

MAR - 3 1995

Re: K950339
Steiner Electromechanic Morcellator
Dated: January 26, 1995
Received: January 27, 1995

Dear Ms. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following additional information:

1. Please provide bench testing that shows that your device can effectively resect tissue without any indications of wear or breakdown. This testing could consist of resecting animal tissue (e.g., beef kidney) through the device for an appropriate length of time.

2. Please provide one of the following: a certification that the device complies with an applicable standard for electromagnetic compatibility, results of testing that demonstrates the device compatibility, or a justification of why you believe neither a certification or testing are necessary.

3. Since the handle of your device will be in the sterile surgical field, and, thus, should be sterilized, please remove the reference in your instructions for use that states that disinfection is an acceptable end reprocessing procedure for the handle.

4. Please either identify what urological procedures would utilize a dextran solution or remove the cleaning statements that relate to dextran from your reprocessing instructions.

5. Please state your validation methods for each type of sterilization procedure described in your instructions.

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), 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 Federal Food, Drug, and Cosmetic Act (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.

The requested information 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 (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If the information 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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Russell Pagano, Ph.D., at (301) 594-2194. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely,

Mark D. Kramer

Mark D. Kramer
Chief, Urology and
Lithotripsy Devices Branch
Division of Reproductive, Abdominal, Ear,
Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

Ms. Marika Anderson
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230

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Dated: January 26, 1995
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2. Please provide one of the following: a certification that the device complies with an applicable standard for electromagnetic compatibility, results of testing that demonstrates the device compatibility, or a justification of why you believe neither a certification or testing are necessary.

3. Since the handle of your device will be in the sterile surgical field, and, thus, should be sterilized, please remove the reference in your instructions for use that states that disinfection is an acceptable end reprocessing procedure for the handle.

4. Please either identify what urological procedures would utilize a dextran solution or remove the cleaning statements that relate to dextran from your reprocessing instructions.

5. Please state your validation methods for each type of sterilization procedure described in your instructions.

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

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Sincerely,

Mark D. Kramer
Chief, Urology and
Lithotripsy Devices Branch
Division of Reproductive, Abdominal, Ear,
Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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[NOT SHOWN ON FINAL LETTER]
bcc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-470 Division
D.O.

RPagano
C:\WP51\FILES\K950339
Draft:3/2/95:ens

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ	Pagano	3/2/95						
HFZ-472	Kramer	3/2/95						

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Memorandum

Date

om REVIEWER(S) - NAME(S) Russ Nagano

Subject 510(k) NOTIFICATION K950339

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

__X__ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

☒ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

__✓__ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: Mark Kramer (BRANCH CHIEF) | UCDB (BRANCH CODE) | 3/2/95 (DATE) (FMF)

FINAL REVIEW: _____ (DIVISION DIRECTOR) _____ (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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

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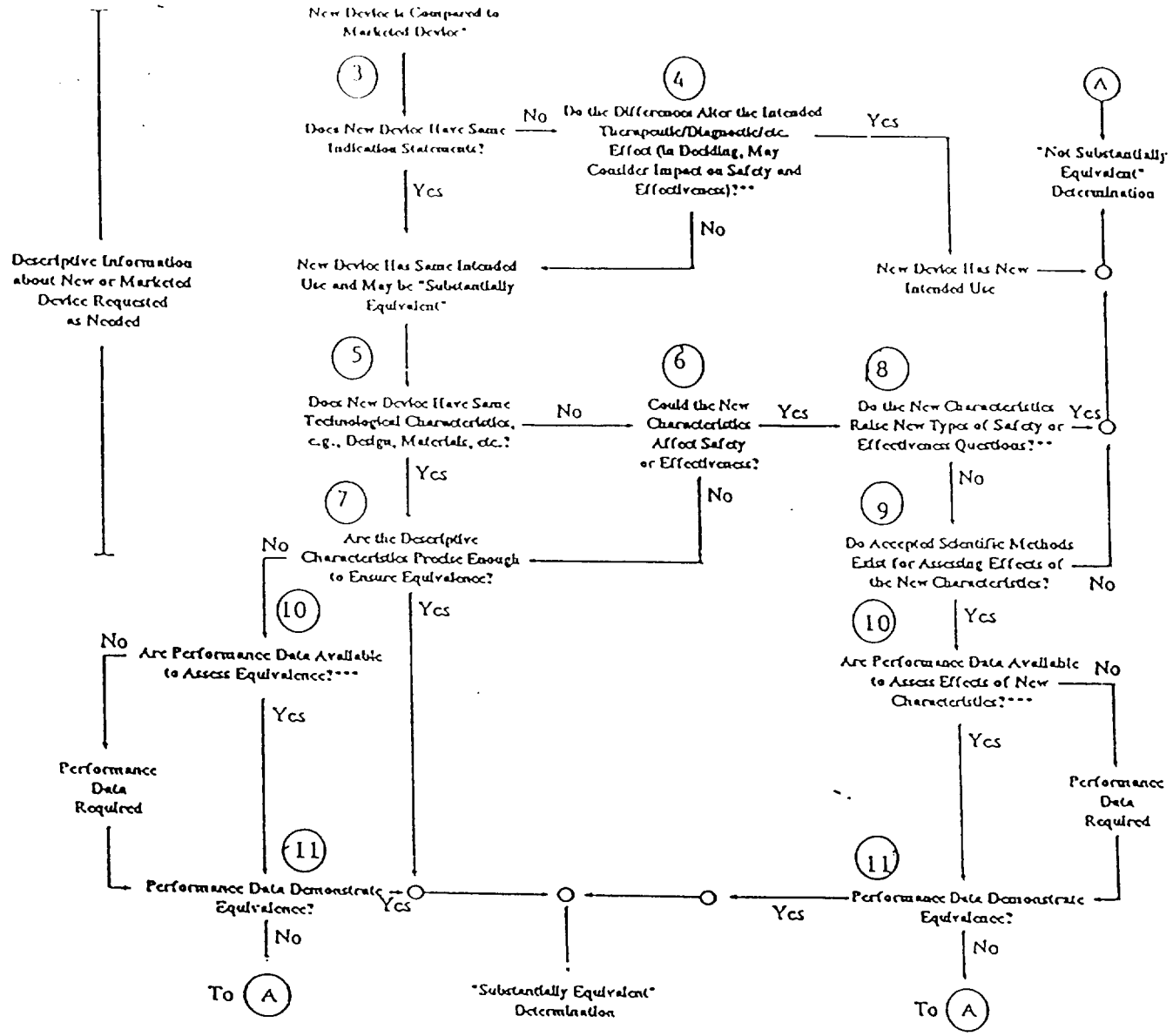
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 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 may be 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 301-796-8118

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RRG/LLD 1/6/93
Rev. 3/30/94

DRAERD Premarket Notification 510(k) Screening Checklist

510(k) Number &
Device Name 950339 - Electromechanic Morcellator

Company KSEA, Inc. Steiner

ITEM	PRESENT Yes	PRESENT No	NEEDED (Y/N/?)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	✓	—	—
Reason for 510(k) - new device or modification	✓	—	—
Identification of legally marketed equivalent device	✓	—	—
2. Proposed Labeling, Labels, Advertisements	✓	—	—
Description of new device/modification	✓	—	—
Intended use statement	✓	—	—
Diagrams, Engineering Drawings, Photographs	✓	—	—
3. Comparison of similarities/differences to named legally marketed equivalent device	✓	—	—
Equivalent Device Labeling, Labels, Advertising	✓	—	—
Intended use of equivalent device	✓	—	—
4. List of all patient contacting materials in new device	✓	—	—
Comparison of materials to equivalent device	✓	—	—
5. Biocompatibility information/data for patient contacting materials, OR	—	—	—
Certification - identical material/formulation	✓	—	—
6. Performance data: Bench data	—	✓	?
Animal data	—	✓	N
Clinical data	—	✓	N
7. Sterilization information	✓	—	—
8. Software validation & verification	—	✓	N
9. 510(k) summary or statement	✓	—	—
10. If Class III, Class III Certification & Summary	—	✓	N
11. If kit, kit certification	—	✓	N

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

Records processed under FOIA #2016-2105 Released by CDRH on 9/2/16

Memo to the Record

Date: March 1, 1995

From: Russell P. Pagano, Mechanical Engineer
Urology and Lithotripsy Branch, DRAERD (HFZ-472)

Subject: K950339 (Tier II)
KSEA Steiner Electromechanic Morcellator
Karl Storz Endoscopy-America, Inc.

Contact: Marika Anderson
Regulatory Affairs Specialist, KSEA
600 Corporate Pointe
Culver City, Ca. 90230
(310) 558-1500 x331
(310) 410-5519 (Fax)

Karl Storz Endoscopy-America, Inc. (KSEA), has submitted a premarket notification for their Steiner Electromechanic Morcellator which they claim is substantially equivalent to devices currently marketed by Cook (K910939), Dyonics (K880150 and K892062), and KSEA's own devices (pre-amendments, K935070, and K940347).

Device Description:

Is the device life supporting or life sustaining?	No
Is the device implanted (short-term or long-term)?	No
Does the device use software?	No
Is the device sterile?	No
Is the device for single use?	No
Is the device for home use?	No
Does the device contain drug or biological products as a component?	No
Is the device a kit?	No

Karl Storz Endoscopy-America, Inc.'s, Electromechanic Morcellator is intended to be used to cut and remove tissue from the body under direct vision open surgical procedures and/or endoscopic procedures including laparoscopic ones. For this application, KSEA is requesting clearance for the device for urological procedures, including nephrectomy. The device had previously been submitted (December 1994) to both the General Surgery (K946213) and Ob/Gyn (K946147) Branches with different procedures listed. General Surgery cleared the device for general surgical use on January 27, 1995, and it is currently under review in the Ob branch.

The morcellator is a motorized reusable device. The tissue cutting and removal system is comprised of the morcellator handle, motor, cutters, sharp obturators (trocars), claw forceps, connecting cord and a multidrive control unit with footswitch. The device has a (b) [redacted]

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

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(b)(4)

[redacted]

To use the device, the operator inserts the sharp obturator through the morcellator handle and into the lumen of the cutter. The morcellator is then inserted directly into the abdomen and the obturator is replaced with the claw forceps. The forceps are then used to grasp a piece of tissue and bring it to the cutting edge of the morcellator which then cuts off a cylindrical piece. The forceps and tissue are then removed, the tissue released, and the forceps reinserted to excise another piece of tissue, until the procedure is completed.

Substantial Equivalence:

Although the predicate devices were cleared for general laparoscopic procedures, the intended use of the proposed device is still to cut and remove tissue from the body under direct vision open surgical procedures and/or endoscopic procedures including laparoscopic ones. The inclusion of specific anatomical sites does not justify a NSE decision on the grounds of different intended use.

The main physical difference between the devices lies in the fact that the proposed device utilizes a

(b)(4)

[redacted]

Another minor difference between these devices lies in the fact that portions of the predicate devices were disposable, while this device is entirely reusable. This is not an issue if the concerns about the cleaning and sterilization procedures (listed below) are addressed.

The accessories included in the 510(k) (obturator, claw forceps) are covered under previous KSEA 510(k) submissions (K935070, K940347).

Electrical Safety:

KSEA states that the control unit of the device complies with applicable IEC 610-1 standards and that the type and degree of protection against electrical shocks complies with UL 544 standards. This is acceptable.

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

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Electromagnetic Compatibility:

KSEA does not address the issue of the electromagnetic compatibility (EMC) of the device. Since this type of device could present EMC concerns, **KSEA should certify that the device complies with an applicable standard for electromagnetic compatibility, provide testing that illustrates the device compatibility, or present a justification of why this testing is not necessary.**

Biocompatibility:

KSEA has certified that the only patient contacting material in these devices is surgical grade stainless steel [redacted] (b)(4) [redacted]. These are the same materials used in the predicate devices. This certification is sufficient for these types of devices.

Sterilization/Reuse:

The devices in this submission are provided non-sterile, which is acceptable for this type of application. KSEA has submitted cleaning and disinfection/sterilization procedures for these instruments. Both steam and ethylene oxide (EtO) gas directions are given. In the directions for use, KSEA states that the morcellator handle can be steam or gas sterilized, or disinfected in cold antiseptic solutions. **Since the handle will be in the sterile surgical field, KSEA should remove the reference to disinfecting procedures as the last step in the handle reprocessing.** The pre-sterilization instructions include very specific care to be taken if a dextran solution had been used. **KSEA should identify what urological procedures would utilize this type of solution or remove these instructions. Finally, KSEA should state what methods of validation are used for each type of sterilization procedure.**

Labeling:

KSEA has submitted instructions for use for the morcellator. An appropriate prescription statement is included, as well as a statement recommending a tissue extraction bag for tissue suspected to be harmful if disseminated in the body and a contraindication that the tool is not to be used on vascularized tissue. Previously, GSDB has required a contraindication on the predicate devices that stated that the devices were not to be used for liposuction. However, since this device utilizes mechanical extraction of tissue (as opposed to a vacuum method), this statement will not be required. Therefore, with the exception of the issues concerning sterilization (see above), the labeling is considered to be acceptable.

510(k) Summary:

In accordance with SMDA 1990, KSEA has submitted a 510(k) Summary.

Recommendation:

I recommend that this application be placed **On Hold** under a listing of **Additional Information (AI)** until KSEA responds to the following deficiencies.

1. Please provide bench testing that shows that your device can effectively resect tissue

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

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without any indications of wear or breakdown. This testing could consist of resecting animal tissue (e.g., beef kidney) through the device for an appropriate length of time.

2. Please provide one of the following: a certification that the device complies with an applicable standard for electromagnetic compatibility, results of testing that illustrates the device compatibility, or a justification of why neither a certification or testing are necessary.

3. Since the handle of your device will be in the sterile surgical field, and, thus, should be sterilized, please remove the reference in your instructions for use that states that disinfecting the handle is an acceptable end reprocessing procedure for the handle.

4. Please either identify what urological procedures would utilize a dextran solution or remove the cleaning statements that relate to dextran from your reprocessing instructions.

5. Please state your validation methods for each type of sterilization procedure described in your instructions.

Russell Pagano concur
Russell Pagano

M J. Cornelius
3/2/95

M Clare
Note- Dr. Jutkins was consulted on this 510(k).
- MK

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

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FOR REVIEWER'S USE ONLY

RRG 9/24/93

DRAERD Premarket Notification 510(k)
SUPPLEMENTAL
Reviewer's Screening Checklist

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: 950339 TIER II

Expedited Review Requested: N Granted: N OR, FDA Identified Expedited: N

ITEM	Yes	No
1. Is the product a device?	Y	
2. Is the device exempt from 510(k) by regulation or policy?		N
3. Are you aware that this device has been the subject of a previous NSE decision?		N
If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)?	—	—
4. Are you aware of the submitter being the subject of an integrity investigation?		N
If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review?	—	—
5. Is there a specific guidance document for this device or device issue(s)?	---	N

In addition, the following item is new to the 510(k) review process. It will not be counted as a screening deficiency since it is new and "unknown" to the industry. It should be identified as a deficiency and requested as part of the technical review. The Explanation of the DRAERD Screening Checklist has been modified to include this information.

6. Address of manufacturing facility/facilities, and if applicable, sterilization site(s).	---	N

Administrative Reviewer Signature: [signature] Date: 01/31/95

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

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DRAERD REVIEWER RECORD FOR 510(K)s, IDEs, AND PMA SUPPLEMENTS

Document Control No._____ Principal Reviewer_____

Date Assigned_____

Consulting reviews designated, as appropriate, by Branch Chief and lead reviewer, at the beginning of the review

Specialty	Review Needed?		Reviewer	Dates	
	Yes	No		Sent	Returned
Clinical	____	____	_____	_____	_____
Engineering/ Physics	____	____	_____	_____	_____
Chemistry/ Biomaterials	____	____	_____	_____	_____
Biological/ Sterility	____	____	_____	_____	_____
Toxicology/ Biocompatibility	____	____	_____	_____	_____
Statistics	____	____	_____	_____	_____
Other_____	____	____	_____	_____	_____

3/93

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

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. DRAERD Quality Control -- to be completed by the Associate Director and, as appropriate, by the designated Medical Officer.

A. Associate Director QC Overview -- medical QC overview of this submission is believed necessary.

YES ___ NO ___

Initials/Date

B. If YES is noted above, Medical Officer QC Overview --

(1) Examination of the specialty reviews indicate there are remaining clinical issues that should be addressed -- see attached sheet for summary.

Initials/Date

(2) In my opinion, all pertinent clinical issues have been adequately addressed.

Medical Officer/Date
Final Signoff

Assoc. Director/Date
Final Signoff

4/93

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 30, 1995

KARL STORZ ENDOSCOPY-AMERICA, INC.
600 COROPORATE POINTE
CULVER CITY, CA 90230
ATTN: MARIKA ANDERSON

510(k) Number: K950339
Received: 27-JAN-95
Product: KSEA STEINER ELECTROMECHANIC MORCELLATOR

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), 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. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
  510(k) Status Coordinator
  Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
  Center for Devices and Radiological Health, FDA
  5600 Fishers Lane
  Rockville, Maryland 20857 USA
  Because of staff limitations, we cannot answer telephone status requests.

- 510(k) status requests should include:
  (1) submitter's name and mailing address;
  (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

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(3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
  (1) the branch to which the 510(k) has been assigned;
  (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
  (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.**

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

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description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

____ fax
____ mail

A. Sponsor Information:

1. Name of 510(k) sponsor: _____

2. Sponsor's mailing address: _____

_____

_____

B. Requester information:

1. Request name: _____

2. Requester affiliation with sponsor: _____

3. Requester mailing address: _____

_____

_____

4. Request fax number (if applicable): _____

5. Requester telephone number: _____

C. 510(k) information:

1. Product name: _____

2. 510(k) number: _____

3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

.....

I certify that the above information is accurate and truthful to the [illegible] of my knowledge.

(Rev:2)

_____
Requester signature

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

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Karl Storz
Endoscopy America, Inc.

600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558 1500

Toll Free 800 421 5463
Fax 310 410 5527

January 26, 1995

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FDA/CDRH/ODE/DMC

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: 510(k) Notification for Karl Storz Endoscopy-America, Inc. Steiner Electromechanic Morcellator and Accessories for use in Urology

Attn: Division of Reproductive, Abdominal, Ear, Nose, Throat and Radiological Devices (DRAERD)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDA Act), Karl Storz Endoscopy-America, Inc. (KSEA) hereby submits this notification for its Steiner Electromechanic Morcellator and Accessories, intended for use during urologic endoscopic surgical procedures. This notification is submitted by KSEA, in response to FDA's letter to medical device manufacturers, dated May 17, 1993, requiring premarket clearance of endoscopic accessories.

Per the requirements outlined in the Safe Medical Devices Act of 1990, KSEA has enclosed a summary of safety and effectiveness in this premarket notification.

KSEA respectfully requests that the contents of this notification be considered confidential per 21 CFR 20.61.

The KSEA Steiner Electromechanic Morcellator is a motorized, reusable surgical device intended for use by qualified surgeons during urologic laparoscopic procedures, including nephrectomy.

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

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The Table of Contents sets forth the outline of this submission, which contains the information required by 21 CFR 807.87.

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RRG/LLD 1/6/93
Rev. 6/7/93

Reviewer's Screening Checklist

510(k) Number &
Device Name Steiner Electromechanic Morcellator and Accessories for use in urology

Company Karl Storz Endoscopy-America, Inc.

ITEM	PRESENT Yes	PRESENT No	NEEDED (Y/N/?)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	X	—	Y
Reason for 510(k) - new device or modification	X	—	Y
Identification of legally marketed equivalent device	X	—	Y
2. Proposed Labeling, Labels, Advertisements	X	—	Y
Description of new device/modification	X	—	Y
Intended use statement	X	—	Y
Diagrams, Engineering Drawings, Photographs	X	—	Y
3. Comparison of similarities/differences to named legally marketed equivalent device	X	—	Y
Equivalent Device Labeling, Labels, Advertising	X	—	Y
Intended use of equivalent device	X	—	Y
4. List of all patient contacting materials in new device	X	—	Y
Comparison of materials to equivalent device	X	—	Y
5. Biocompatibility information/data for patient contacting materials	X	—	Y
Certification - identical material/formulation	—	X	N
6. Performance data: Bench data	—	X	N
Animal data	—	X	N
Clinical data	—	X	N
7. Sterilization information	X	—	Y
8. Software validation & verification	—	X	N
9. 510(k) summary or statement	X	—	Y
10. If Class III, Class III Certification & Summary	—	X	N
11. If kit, kit certification	—	X	N

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I. Name of Device

Proprietary Product Name: KSEA Steiner Electromechanic Morcellator

Common/Usual Name: Tissue Morcellator

Classification Name: Accessory to Endoscope

II. Establishment Registration Number

KSEA is the initial importer of these instruments. The establishment registration number for KSEA is 2020550.

III. Class Of Device

The FDA has classified instruments of this type and intended use in 21 CFR 876.1500 as Class II devices, under the product category of Accessories to Endoscopes.

IV. Performance Standards

No performance standards or special controls have been established by FDA under section 514 of the FDC Act.

V. Labeling

Representative draft literature for the KSEA Steiner Electromechanic Morcellator is included in Enclosure 1 of this submission.

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

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VI. Description of the Device and Intended Use

The KSEA Steiner Electromechanic Morcellator is a motorized, reusable surgical device. The device is intended for use by qualified surgeons during the endoscopic surgical procedure. As described more fully below, the KSEA Steiner Electromechanic Morcellator presented in this notification is intended to be used during urologic laparoscopic procedures, including nephrectomy. KSEA representative draft labeling is provided in Enclosure 1. Instructions for cleaning and disinfection may be found in Enclosure 3. Supporting literature for the use of these accessories to endoscopes is provided in Enclosure 4.

The Steiner Electromechanic Morcellator is a reusable motor driven tissue cutting and removal system comprised of the morcellator handle, motor, cutters, sharp obturators (trocars), claw forceps, connecting cord and multidrive control unit with footswitch. The device consists of a 12 mm diameter, 20 cm long cannula attached to the handle which houses the motor, which in turn is connected to the control unit by means of a connecting cable. The cutter is a circumferentially sharpened tube 11 mm in diameter with a 20 cm working length, which fits inside the cannula through the handle and is locked into place with a locking ring. The cutting edge may be rotated up to a maximum speed of 300 rpm in a clockwise or counterclockwise direction or may oscillate between the two via use of the footswitch. The footswitch has two pedals; the right pedal rotates the cutter clockwise, the left pedal rotates the cutter counterclockwise and pressing both pedals simultaneously results in oscillation. The sharp obturators are available with either conical or pyramidal tips and are 10 mm in diameter and 29.5 cm in length. The claw forceps are 10 mm in diameter and 36 cm in length with 2 x 3 teeth. All body contact portions of the KSEA Steiner electromechanic morcellator are manufactured from AISI series 303 or 304 surgical grade stainless steel, with the exception of the forcep jaws which are series 420.

The control unit features power switch, speed range control, pilot lights that indicate the direction of rotation, connection ports for the cables to the footswitch and morcellator motor. The motor connector cord is an insulated, two conductor, nonshielded cable with miniature RCA type connectors with gold leads. The control unit designs comply with applicable IEC 601-1 standards for medical devices of this nature. The type and degree of protection against electrical shocks complies with UL 544 standards.

The sharp obturator is inserted through the silicone rubber gasket on the morcellator handle and into the lumen of the cutter. The morcellator is inserted directly into the abdomen, the sharp obturator is withdrawn from the morcellator and the clawed forceps are inserted through the cutter. The forceps grasp the dissected tissue to be removed and pull it to the rotating cutting edge of the morcellator which cuts off a cylindrical block of tissue. This excised piece of tissue is removed from the cutter lumen with the forceps. This process is repeated until the entire piece of tissue has been morcellated and removed. The KSEA Steiner electromechanic morcellator is intended to be used during urologic laparoscopic procedures, including nephrectomy.

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

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VII. Substantial Equivalence

A. KSEA Steiner Electromechanic Morcellator

The KSEA Steiner Electromechanic Morcellator is substantially equivalent to devices currently legally marketed by Cook, Dyonics and KSEA. The KSEA Steiner Electromechanic Morcellator presented in this notification is intended to be used during urologic laparoscopic procedures, including nephrectomy. A comparison of device characteristics is presented in the Substantial Equivalence Table, which is provided in Part B of this section. KSEA representative draft labeling is provided in Enclosure 1. Marketing literature for the currently marketed predicate devices is provided in Enclosure 2.

The Steiner Electromechanic Morcellator is a reusable motor driven tissue cutting and removal system comprised of the morcellator handle, motor, cutters, sharp obturators (trocars), claw forceps, connecting cord and multidrive control unit with footswitch. The device consists of a 12 mm diameter, 20 cm long cannula attached to the handle which houses the motor, which in turn is connected to the control unit by means of a connecting cable. The cutter is a circumferentially sharpened tube 11 mm in diameter with a 20 cm working length, which fits inside the cannula through the handle and is locked into place with a locking ring. The cutting edge may be rotated up to a maximum speed of 300 rpm in a clockwise or counterclockwise direction or may oscillate between the two via use of the footswitch. The footswitch has two pedals; the right pedal rotates the cutter clockwise, the left pedal rotates the cutter counterclockwise and pressing both pedals simultaneously results in oscillation. The sharp obturators are available with either conical or pyramidal tips and are 10 mm in diameter and 29.5 cm in length. The claw forceps are 10 mm in diameter and 36 cm in length with 2 x 3 teeth. All body contact portions of the KSEA Steiner electromechanic morcellator are manufactured from AISI series 303 or 304 surgical grade stainless steel, with the exception of the forcep jaws which are series 420.

The control unit features a power switch, speed range control, pilot lights that indicate the direction of rotation, connection ports for the cables to the footswitch and morcellator motor. The motor connector cord is an insulated, two conductor, nonshielded cable with miniature RCA type connectors with gold leads. The control unit designs comply with applicable IEC 601-1 standards for medical devices of this nature. The type and degree of protection against electrical shocks complies with UL 544 standards.

The sharp obturator is inserted through the silicone rubber gasket on the morcellator handle and into the lumen of the cutter. The morcellator is inserted directly into the abdomen, the sharp obturator is withdrawn from the morcellator and the clawed forceps are inserted through the cutter. The forceps grasp the dissected tissue to be removed and pull it to the rotating cutting edge of the morcellator which cuts off a cylindrical block of tissue. This excised piece of tissue is removed from the cutter lumen with the forceps. This process is repeated until the entire piece of tissue has been morcellated and removed. The KSEA Steiner electromechanic morcellator and accessories is intended to be used during urologic laparoscopic procedures, including nephrectomy.

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

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The KSEA Steiner Electromechanic Morcellator is substantially equivalent to predicate devices legally marketed by Cook (K925851). The Cook Tissue Morcellator is a sterile, single use, disposable motorized tissue cutting and removal device with a reusable motor assembly and power supply. This device is comprised of a cannula, morcellator blade, morcellator body, tissue collection chamber, vacuum control valve, motor assembly, power supply with footswitch. The cutter is a circumferentially sharpened tube 11 mm in diameter and 13.5 cm in length which fits inside the cannula. The cutting edge is rotated at a fixed rate of 4,000 to 5,000 rpm via use of the footswitch. All body contact portions of the Cook Tissue Morcellator are manufactured from surgical grade stainless steel. The Cook power supply assembly features a power switch.

The Cook tissue morcellator is inserted through an incision into the abdomen, the vacuum and morcellator blade are activated and the device is advanced into the tissue to be morcellated. The vacuum pulls the tissue into contact with the morcellator blade and subsequently into the morcellator cannula. The excised tissue is removed by vacuum from the cutter lumen into the tissue collection chamber. The Cook Tissue morcellator is intended for the removal of dissected tissue under direct vision open surgical procedures and/or endoscopic procedures including laparoscopic and pelviscopic procedures.

The KSEA Steiner Electromechanic Morcellator is substantially equivalent to predicate devices legally marketed by Dyonics (K892062). The Dyonics arthroscopic surgical system is a reusable motorized tissue cutting and removal device with motor drive and control unit. This device is comprised of a cannula, morcellator blade, motor assembly and power supply with footswitch. The cutter is a circumferentially sharpened tube 3.5 - 5.5 mm in diameter; length is unavailable. The cutting edge is rotated at an unknown rate via use of the footswitch. All body contact portions of the Dyonics device are manufactured from surgical grade stainless steel. The control unit features include a power switch, speed control and connection ports for the cables to the footswitch and the morcellator motor drive.

The Dyonics tissue morcellator is inserted through an incision into an articular cavity, the vacuum and morcellator blade are activated and the device is advanced into the soft tissue to be morcellated. The vacuum pulls the tissue into contact with the morcellator blade and subsequently into the morcellator cannula. The excised tissue is removed by vacuum from the cutter lumen into an outside tissue collection container. The Dyonics arthroscopic surgical system is indicated for removal of damaged tissue in articular cavities during arthroscopic procedures. Despite the fact that the predicate device is intended for use in arthroscopy and the KSEA device is intended for use in urology , both devices have the same intended use of cutting and removing tissue from the body.

The KSEA obturators used with the Steiner Electromechanic Morcellator are substantially equivalent to predicate devices marketed by KSEA prior to May 28, 1976. The pre-1976 predicates were available in diameters ranging from 7 to 11 mm, with pyramidal tips and were manufactured from surgical grade stainless steel. These devices were intended to create an incision into the patients body to allow insertion of a cannula prior to endoscopic procedures.

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

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The KSEA claw forceps used with the Steiner Electromechanic Morcellator are substantially equivalent to the KSEA claw forceps that have been previously cleared by the 510(k) process. Both devices are 10 mm in diameter, 36 cm in length with 2 x 3 teeth and jaws made of series 420 surgical grade stainless steel. Both of these devices are intended for use in urologic endoscopic procedures.

The KSEA obturators used with the Steiner Electromechanic Morcellator are substantially equivalent to predicate devices marketed by KSEA prior to May 28, 1976. The pre-1976 predicates were available in diameters ranging from 7 to 11 mm, with pyramidal tips and were manufactured from surgical grade stainless steel. These devices were intended to create an incision into the patients body to allow insertion of cannula prior to urologic endoscopic surgery.

The KSEA Steiner Electromechanic Morcellator and the predicate morcellator devices are similar in body contact materials and design so no new issues of safety and effectiveness are raised. All of the devices are motorized, foot pedal controlled and feature a surgical grade stainless steel cannula with a rotary cutting blade. The KSEA subject device and the Cook predicate device are similar in dimensions. The Dyonics device has a smaller diameter due to the fact that this device is designed to access small areas within joints. There are no safety issues regarding potential hazards involving the use of vacuum for the KSEA subject device as there are for the Cook and Dyonics device. The KSEA and Cook devices have the same intended use of removing and morcellating tissue in laparoscopic procedures. Although the KSEA and Dyonics devices are intended for use in different anatomical locations, both devices have the same intended use of morcellating and removing tissue from the surgical site in endoscopic procedures.

The KSEA sharp obturators for use with the Steiner Electromechanic Morcellator are similar in body contact materials, dimensions and design to the KSEA Pre-1976 predicate trocars so no new issues of safety and effectiveness are raised. These devices have the same intended use of creating an incision into the patients body to allow insertion of a cannula prior to urologic endoscopic surgery.

The KSEA claw forceps for use with the Steiner Electromechanic Morcellator are identical in body contact materials, dimensions and design to the KSEA forceps so no new issues of safety and effectiveness are raised. Both of these devices are intended for use in urologic endoscopic surgery.

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

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B. Substantial Equivalence Table

KSEA has compared its subject endoscopes with similar devices that have been manufactured by several other companies and cleared by the 510(k) notification process. This comparative information is provided in this section. Substantial equivalence is supported by the following data.

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

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KARL STORZ STEINER ELECTROMECHANIC MORCELLATOR AND EQUIVALENT PRODUCTS

MANUFACTURER AND DEVICE	DIMENSIONS	TISSUE REMOVAL METHOD	TYPE OF CUTTER	MATERIAL	INTENDED USE
Karl Storz Steiner Electromechanic Morcellator	**13 mm diameter, 20 cm length**	**Mechanical**	**Rotary**	**Series 303 or 304 Surgical Grade Stainless Steel**	**Morcellation and removal of tissue during urologic endoscopic procedures, including laparoscopic nephrectomy**
Cook (K925851) Tissue Morcellator	10 mm diameter, 14 cm length	Vacuum	Rotary	Surgical Grade Stainless Steel	Morcellation and removal of dissected tissue under direct vision open surgical procedures and/or endoscopic procedures including laparoscopic and pelviscopic procedures
Dyonics (K892062) Advanced Arthroscopic Surgical System	3.5 - 5.5 mm diameter, length unavailable	Vacuum	Rotary	Surgical Grade Stainless Steel	Resect damaged tissue and remove extraneous matter in articular body cavities
Karl Storz Sharp Obturators	**10 mm diameter**	**N/A**	**N/A**	**Series 303 or 304 Surgical Grade Stainless Steel**	**To create incision to allow insertion of cannula prior to urologic endoscopic surgery**
Karl Storz Trocars (K940347)	7 - 11 mm diameter	N/A	N/A	Same	Same
Karl Storz Claw Forceps	**10 mm diameter, 36 cm length**	**N/A**	**N/A**	**Series 420 surgical grade stainless steel**	**To grasp tissue during urologic endoscopic procedures**
Karl Storz Claw Forceps (K935070)	10 mm diameter, 36 cm length	N/A	N/A	Series 420 surgical grade stainless steel	Same

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

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VIII. Additional Information

A. Sterilization and Cleaning

The KSEA Steiner Electromechanic Morcellator is sold non-sterile and is reusable. KSEA recommends that before use, reuse and sterilization, meticulous cleaning of these instruments should be performed by the user. Additional supporting information for the sterilization of the KSEA Steiner Electromechanic Morcellator and accessories is provided in Enclosure 1.

B. Biocompatibility

The working elements of the KSEA Steiner Electromechanic Morcellator and accessories come into contact with the patient for brief periods of time. All components which come into body contact are constructed of surgical grade stainless steel. The material(s) used in these instruments is commonly used in medical devices for a wide range of applications and have a long history of biocompatibility for human use.

C. Scientific Journal Articles

Scientific journal articles and additional supporting literature is provided in Enclosure 4.

IX. Confidentiality

The existence of this submission and certain information contained within may be trade secret, or confidential commercial or financial information within the meaning of 21 CFR 20.61. KSEA has maintained the existence of this submission as confidential commercial information and has not disclosed this submission to anyone except its employees, consultants, and law firms. KSEA respectfully requests that the FDA consider the contents of this submission confidential and requests that FDA consult with KSEA prior to releasing any information contained in this submission.

X. 510(k) Summary of Safety and Effectiveness Information

In response to the Safe Medical Devices Act of 1990, a 510(k) Summary of Safety and Effectiveness Information is provided in Enclosure 5.

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

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XI. Contact Person

We believe that substantive information necessary to enable FDA to find the products subject of this notification substantially equivalent with legally marketed devices has been provided in this document. In the event that additional clarification or information is needed, please contact Marika Anderson, Regulatory Affairs Specialist, KSEA, at 600 Corporate Pointe, Culver City, CA. 90230; telephone: (310) 558-1500 Ext. 331, FAX: (310) 410-5519.

Best regards,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

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

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KARL STORZ REPRESENTATIVE DRAFT LITERATURE

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DRAFT

CAUTION: Federal law restricts this device to sale by or on the order of a physician

CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the surgeon may consider to be harmful when disseminated in a body cavity.

CAUTION: This device is specifically contraindicated for use on vascularized tissue as a dissecting tool.

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STEINER Electromechanic Morcellator

STORZ
KARL STORZ — ENDOSKOPE

STEINER Electromechanic Morcellator

Endoscopic interventions which are necessary to remove large sections of tissue still represent a challenge for minimally invasive surgery. Although several extraction techniques are now available specifically for removing large tissue quantities, this procedure is usually very time-consuming and often requires enlargement of the incision or even an additional incision

In contrast, the Electromechanic Morcellator makes it easy to remove even relatively large sections of tissue from the abdomen in only a few minutes through the existing incisions.

The Electromechanic Morcellator consists of a motor-driven cutting tube which can be inserted direct into the abdomen without an additional trocar cannula. The speed of rotation is preselectable in 3 steps and can be triggered via a footswitch. There is the option of clockwise, counterclockwise and oscillating rotation.

Clawed forceps for gripping the tissue to be extracted are inserted into the abdomen through the cutting tube. If the forceps are then pulled back, pressing the tissue against the cutting edge of the rotating morcellator, a cylindrical block of tissue can be cut out and removed through the tube by applying a measured pulling force and, if necessary varying the speed and direction of rotation. In this way even large tissue quantities can be removed within few minutes.

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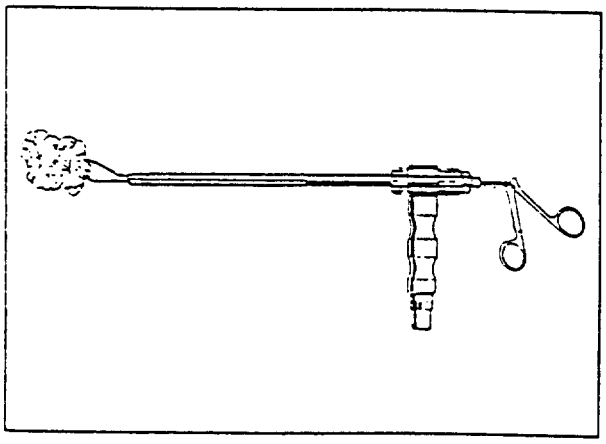
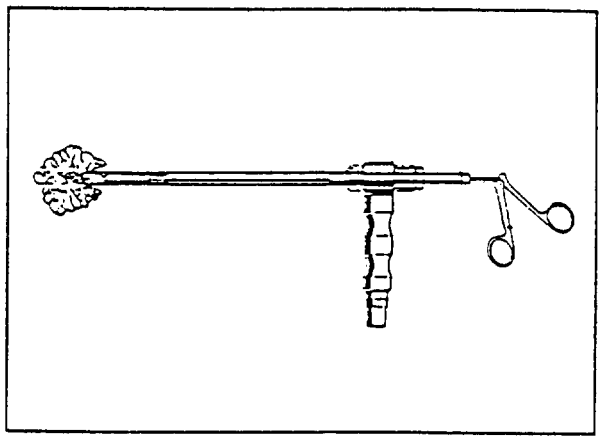


The tissue is gripped by forceps passed through the cutting tube.



The tissue is pressed against the rotating cutting tube by pulling back the forceps and in this way a cylindrical section of tissue is cut out, which can then be easily extracted.

SS

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STEINER Electromechanic Morcellator

size 12 mm.

For use with trocars, size 13 mm.

KARL STORZ — ENDOSKOPE

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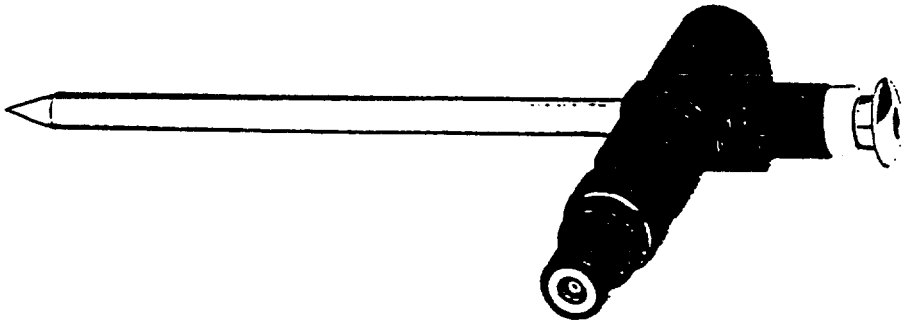

26712011 STEINER Electromechanic Morcellator, consisting of:

- 26712031 1 Morcellator Handle, 300 rpm. max.
- 20712030 1 Motor.
- 26712040 2 Cutters
- 26712041 1 Obturator with conical tip.
- 26712042 1 Obturator with pyramidal tip.
- 26712070 1 Connecting Cord for connecting the MULTIDRIVE control unit with motor 20712030.
- 30422 FS 1 Take-apart® Claw Forceps, 2 x 3 teeth, consisting of:
  - 30552 Metal-Handle.
  - 30540 Outer Tube.
  - 30420 FS Claw Forceps.

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MULTIDRIVE Control Unit

'or use with STEINER Electromechanic Morcellator.

STORZ
KARL STORZ — ENDOSKOPE

Special features:

- Speed of rotation preselectable in 3 steps.
- 3 footswitch functions:
  clockwise, counterclockwise and oscillating rotation (clockwise-counterclockwise).
- The modular design makes it easy to clean and sterilize the single components.

Specifications:

Dimensions:	305 mm x 105 mm x 233 mm (w x h x d).
Weight:	approx. 5 kg.
Design:	according to IEC 601-1.

DRAFT

20712001 **MULTIDRIVE Control Unit,**
power supply: 100–240 VAC, 50/60 Hz
consisting of:

400 A	1 **Mains Cord.**
20712020	1 **MULTIDRIVE Unit.**
20010430	1 **Two-Pedal Footswitch.**

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Instruction Manual – preliminary –	STORZ KARL STORZ – ENDOSKOPE	Date: September 94

DRAFT

Instruction Manual

STEINER Electromechanic Morcellator Model 267120 11

MULTIDRIVE Control Unit Model 207120 20

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Instruction Manual – preliminary –	STORZ KARL STORZ – ENDOSKOPE	Date: September 94

Operating elements, displays, connectors and their uses

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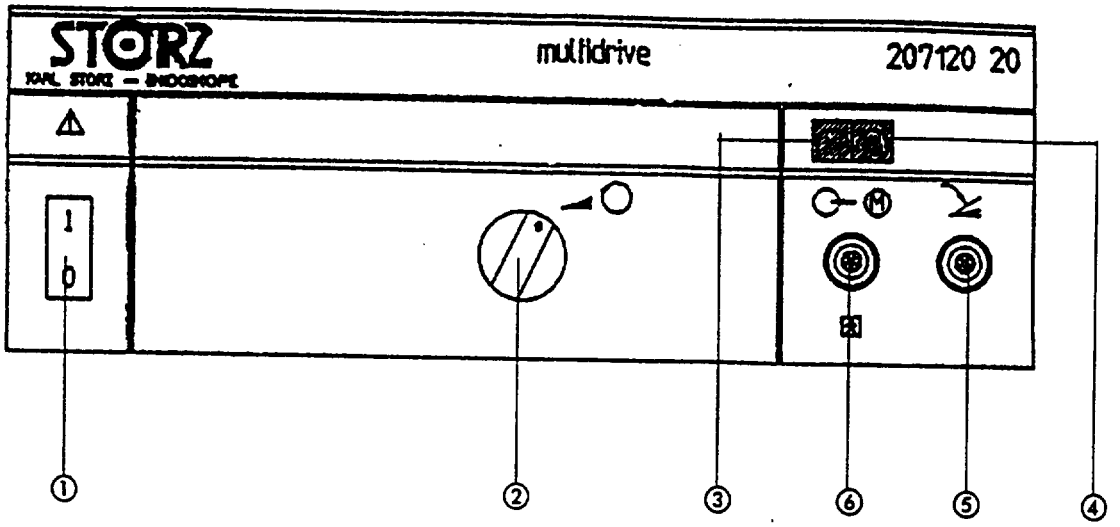

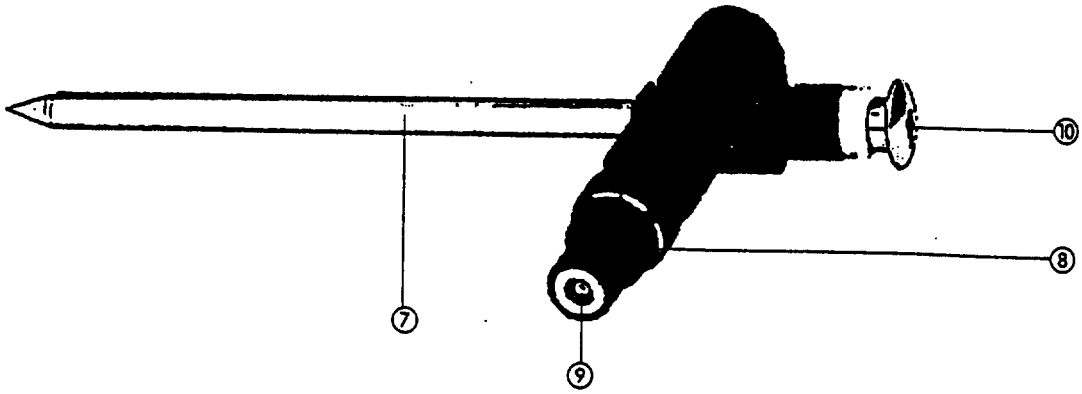

① Power switch
② Speed range control
③ Pilot lamp for counterclockwise rotation
④ Pilot lamp for clockwise rotation
⑤ Connector for footswitch
⑥ Connector for handle
⑦ Morcellator
⑧ Handle with motor inserted
⑨ Connector for connecing cable to the control unit
⑩ Obturator

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

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Cautions:

- DANGER: Risk of explosion if used in the presence of flammable anesthetics
- CAUTION: To reduce the risk of electrical shock, refer servicing to qualified service personnel
- CAUTION: Cutting tube is sharp-edged. Damage to tissue can also result when cutting tube is not activated. Insert cutting tube only under visual observation.
- Read the instructions carefully before operating the unit
- Keep out of reach of patients

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Installation and operation of the unit

1. Connect power cord. Insert the power cord into power connector as far as it will go. Connecting the instrument to the power line should only be carried out outside potentially explosive locations.

2. Plug the footswitch cable into socket ⑤ as far as it will go.

DRAFT

3. Push the motor into the morcellator handle ⑧ until it locks into place.

4. Connect the motor ⑨ to the control unit using the connecting cable supplied.

5. Switch on power switch ①.

6. Set the desired speed range on switch ②.

7. The direction of rotation is controlled with the footswitch:

Left pedal:	counterclockwise (pilot lamp ③ illuminates)
Right pedal:	clockwise (pilot lamp ④ illuminates)
Left and right pedal:	Oscillation (pilot lamps ③ and ④ illuminates alternately)

In the oscillation mode the direction of rotation changes 2 times within a second. It is advisable to switch to this operating mode whenever the morcellator has jammed.

Note: To prevent the motor from overheating, the oscillation mode is limited to a period of 5 seconds.

Inserting the morcellator

1. Insert the cutting tube into the abdomen.

2. To remove tissue, a claw forceps is intoduced via the cutting tube.

3. The tissue is pressed against the rotating cutting tube by pulling back the forceps and in this way a cylindrical section of tissue is cut out, which can then be easily extracted.

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Changing the cutting knife

Caution: Always pull out the power plug beforehand!

1. Unscrew the black screw cap at the proximal end of the handle.
2. Remove the larger screw cap at the distal end of the handle. The cutting knife can now be pulled out.
3. Insert the new cutting knife. Then reassemble the handle in reverse sequence.

Fuse replacement

Caution: Always pull out the power plug beforehand!

1. Remove the power fuse holder with a screwdriver or other tool.
2. Insert new fuses of the appropriate rating.
3. Replace power fuse holder.

Cleaning and care of the unit

Caution: Always pull out power plug before cleaning.

The instrument surface should be cleaned with a mild cleaning agent or disinfectant. Do not allow any cleaning liquid to get into the instrument.

The morcellator handle and the motor may be steam or gas sterilized, or disinfected in cold antiseptic solutions.

The connecting cord may be steam or gas sterilized.

Do not disinfect the connecting cord in antiseptic solutions.

Manufacturer's warranty

For one year as of delivery to the end customer we agree to replace the goods free of charge if proof can be provided of faulty materials or faulty workmanship. In doing so we cannot accept to bear the cost of transportation or the risk of shipment. The warranty referred to in § 3 of our Standard conditions of Business shall apply.

Opening the equipment or performance of any repairs or modifications of the equipment by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair or modification during the warranty period shall void all warranty.

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Specifications (MULTIDRIVE Control Unit)

Power supply voltage:	100/120/230/240 VAC
Power frequency:	50/60 Hz
Oscillation frequency range	80 – 390 rpm
Operating temperature:	10 °C – 40 °C (50 – 104 °F)
Storing temperature:	0 °C – 60 °C (32 – 140 °F)
Dimensions:	305 mm x 109 mm x 271 mm (w x h x d)
Weight:	5.0 kg
Design:	According to IEC 601-1

Equipment classification:

Degree of waterproofing:
Drip-proof per IPX 1

Type of protection against electric shocks:
Protection class 1

Degree of protection against electric shocks:
BF-type instrument

The type and degree of protection against electrical shocks complies with UL 544 standards

Cor

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Instruction Manual – preliminary –	STORZ KARL STORZ – ENDOSKOPE	Date: September 94

General circuit diagram

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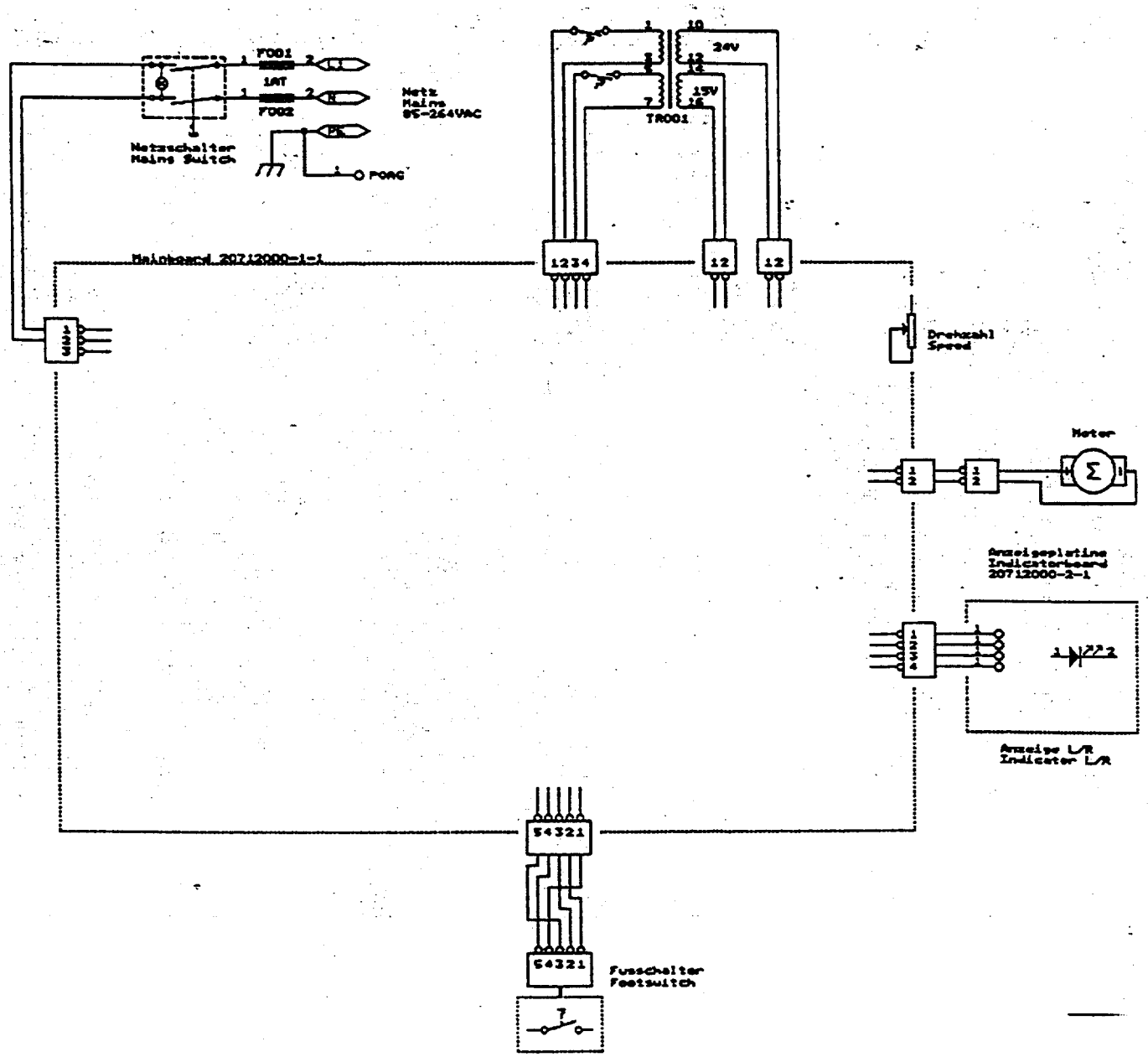

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PREDICATE LITERATURE

COOK

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Cook® Tissue Morcellator™

Description:

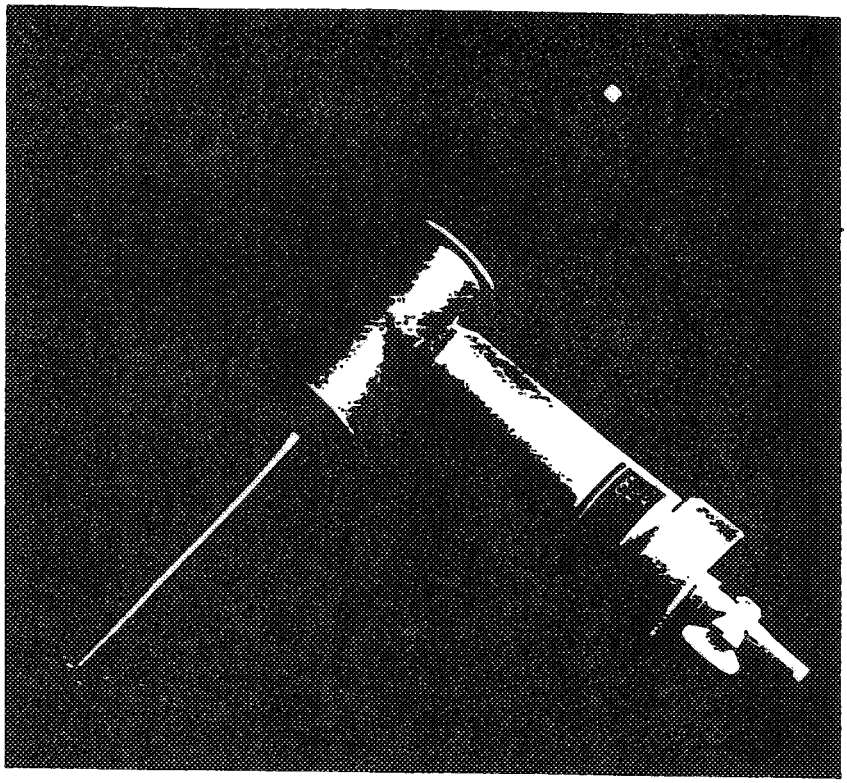
Morcellator body assembly with stainless steel cutting cannula and vacuum control valve

Cook® Series 1 Tissue Morcellator™ Power Supply Assembly includes Series 1 power supply with cord, foot switch with motor cable, and tissue morcellator motor assembly in a storage case; non-sterile

The Cook® Tissue Morcellator™ is used for the morcellation and removal of dissected tissue under direct vision, open surgical procedures, and/or endoscopic procedures when used in conjunction with the LapSac™.

The action of the Morcellator™ is based upon a combination of a circumferentially sharpened cutting cannula (patent pending) and a hospital house vacuum. The stationary outer sheath has an angular opening which protects the LapSac™ (organ entrapment system featured on next page) from contacting the inner cutting cannula blade.

The Cook® Tissue Morcellator™ has an electric motor which drives the inner cutting cannula at a fixed rate of 4,000 to 5,000 r.p.m. The motor is reusable, non-sterile, and does not come into contact with tissue or body fluids. The collection chamber filter is bonded to the vacuum control valve/handle. The handle is capable of holding 184 ml of morcellated tissue without interruption to empty.



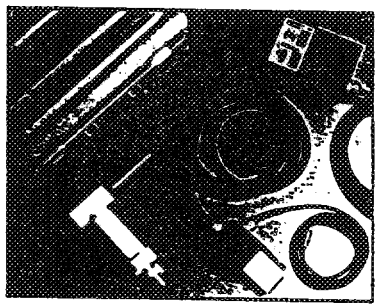
The Morcellator™ can be an effective tool in the reduction of surgical trauma related to the removal of dissected tissue.

The Cook® Tissue Morcellator™ is supplied sterile in peel-open packages and is intended for one-time use.

Note: The Cook® Series 1 Tissue Morcellator™ Power Supply Assembly must be ordered separately.

For order information see page 31.

Patent Pending



Cook® Tissue Morcellator™, power supply assembly and storage case.

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

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COOK® TISSUE MORCELLATOR™

Operators Manual

CAUTION: The Cook® Tissue Morcellator™ is intended for use by physicians trained and experienced in techniques for tissue morcellation.

MRCL693

COOK UROLOGICAL INCORPORATED
A COOK GROUP COMPANY
1100 West Morgan Street P.O. Box 227
Spencer, Indiana 47460 U.S.A.
Phone: 812 829-4891 Telefax: 812 829-2022
Toll Free: 800 457-4448

COOK OB/GYN®
A DIVISION OF COOK UROLOGICAL INC.
1100 West Morgan Street P.O. Box 271
Spencer, Indiana 47460 U.S.A.
Phone: 812 829-6500 Telefax: 812 829-2022
Toll Free: 800 541-5591

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Cook® Tissue Morcellator™ Body Assembly

Cook Urological®
Order Number: 410010

Cook Ob/Gyn®
Order Number: KCTM-410010

The Cook® Tissue Morcellator™ Body Assembly is supplied sterile in peel-open packages and is intended for one-time use.

Description:
Polyvinylchloride morcellator and tissue collection chamber with vacuum control valve and stainless steel cutting cannula assembly

Stainless steel collection chamber filter

Polyurethane sterility sleeve 200 cm long

Cook® Series 1 Tissue Morcellator™ Power Supply Assembly

Cook Urological®
Order Number: 410000

Cook Ob/Gyn®
Order Number: KCTM-410000

Components: (Supplied non-sterile)

Cook® Series 1 Power Supply
- Line voltage: 120 V AC
- Line Frequency: 60 Hz
- Line Current: 1 A
- Output: 24 V DC, 100 VA
- Output is electrically isolated

Power cord

Foot switch

Motor cable with waterproof connector

Cook® Series 1 Tissue Morcellator™ Motor Assembly

Contraindications:

The Cook® Tissue Morcellator™ is contraindicated for the morcellation of bone and for use in liposuction procedures.

Precautions and Warnings:

The Cook® Tissue Morcellator™ should be used during laparoscopic, pelviscopic and percutaneous procedures only by physicians with adequate training in these procedures.

A comprehensive preoperative medical history and physical examination are suggested. Radiographic evaluation and laboratory tests may be included.

The Cook® Tissue Morcellator™ will cut and aspirate tissue when vacuum is applied in combination with blade rotation and direct contact with tissue. **WARNING: Do not place the blade in contact with tissue which is not intended to be morcellated.**

Direct contact of the rotating cutting edge of the blade with metal (e.g.: cannula, endoscope, or other instruments) can cause damage to the morcellator blade. If such contact should occur, the entire morcellator body assembly should be discarded and a new unit substituted. Replacement blades are not available for the morcellator.

Patent Pending

Questions? Contact FDA/CDRH/OCE/DBA/CDRH/OIS/ASSB/Ms. Sabrina Ingram 301-796-8118

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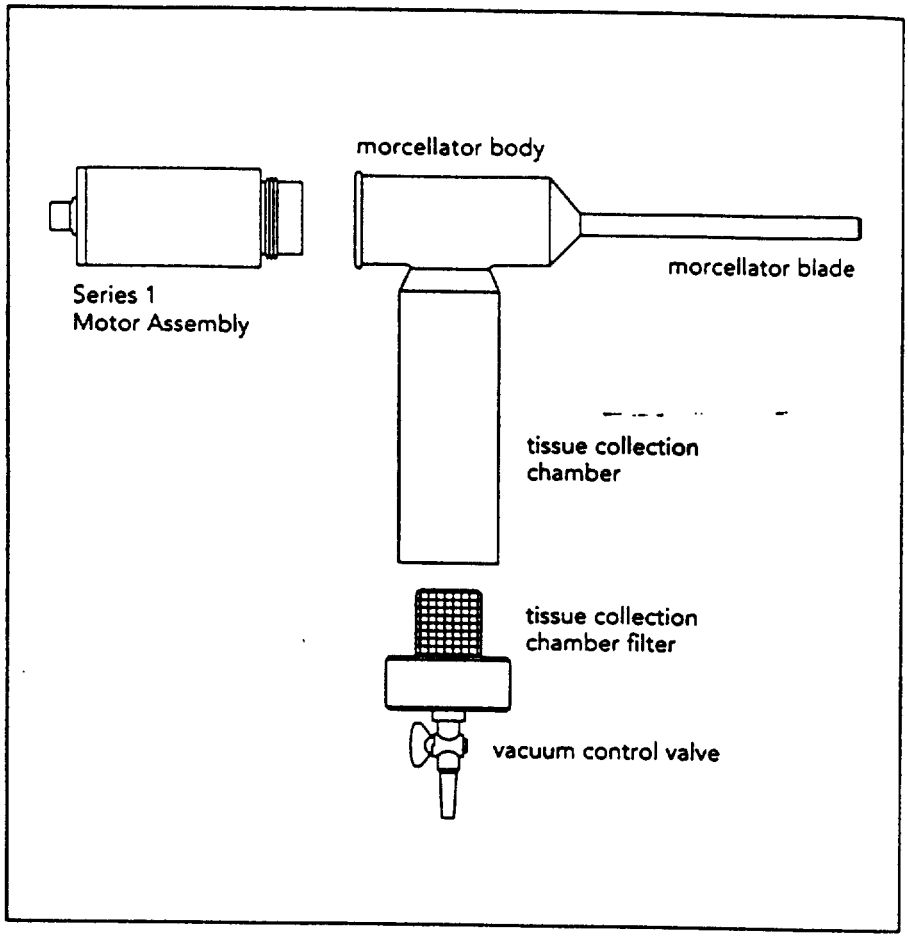

The Cook® Tissue Morcellator™ rotary scalpel is used for morcellation and removal of dissected tissue under direct vision, open surgical procedures, and/or endoscopic procedures when used in conjunction with the LapSac™.

Operator Instructions:

DANGER: Risk of explosion. Do not operate the morcellator in the presence of flammable anesthesia and other volatile materials.

WARNING: Electrical shock hazard. Do not attempt to remove the cover from the power supply assembly, or disassemble the morcellator motor.

If the power supply or motor fail to perform properly, contact Customer Service (800 457-4448 or 800 541-5591) for a return authorization.

In the event that you must return the power supply assembly for service, it should be cleaned and packed in the original case for shipping.

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Assembly:

1. In the sterile field, remove the morcellator body assembly from the sterile packaging.

2. In the sterile field, attach the non-sterile motor assembly to the morcellator body, taking care to avoid entangling the sterility sleeve in the motor threads.

3. Attach the non-sterile motor cord to the motor assembly. **CAUTION: The Series 1 Motor Assembly is intended for use with a Cook® Series 1 Power Supply only. Do not attempt to substitute other power supplies.**

4. Pull the sterility sleeve over the motor and cord.

5. Maintaining the sterile field, attach vacuum tubing to the vacuum control valve on the morcellator. Connect vacuum tubing to wall suction (20 to 28 in. Hg).

6. Plug the power cord to a hospital grade receptacle and position the foot pedal switch appropriately.

7. The device is now ready for use.

Operation:

1. The circuit breaker, located on the Power Supply Assembly, must be in the on position to power the morcellator. The circuit breaker will switch to the off position in the event of a fault.

2. Open the vacuum control valve on the morcellator body.

CAUTION: Direct application of vacuum to an insufflated peritoneum will result in loss of insufflation medium. Morcellator must be used in conjunction with a LapSac™ during endoscopic procedures. Not recommended for use with other tissue isolation products.

3. Depress foot pedal to activate morcellator blade. The foot pedal is a threshold switch; morcellator blade speed is constant. To stop blade, release foot pedal switch. **NOTE: The vacuum control valve and foot pedal can be turned on and off at the physician's discretion throughout the procedure.**

4. Advance morcellator cannula directly into tissue to be morcellated. To achieve optimal morcellation use measured, methodical strokes in favor of forcibly driving the sheathed rotary scalpel into tissue. Continue until desired morcellation is complete.

WARNING: The LapSac™ can be cut if manual tension is not maintained. The assisting surgeon must maintain manual tension to prevent folds of the LapSac™ from being drawn into the morcellator. The LapSac™ should be monitored by video throughout the morcellation.

5. To remove tissue from collection chamber:

a. Close vacuum control valve.

b. Remove base from the tissue collection chamber.

Disassembly:

1. Turn off wall suction.

2. Unplug power cord from wall outlet.

3. Remove the sterility sleeve and disconnect the motor cable from the morcellator motor.

4. Disconnect the vacuum tube from the vacuum control valve.

5. Remove the motor from the morcellator body.

6. Dispose of the morcellator body properly.

Morcellator Motor and Power Supply Assembly Cleaning Instructions:

CAUTION: Do not attempt to sterilize the motor or power supply assembly by steam autoclave, ethylene oxide gas (ETO), or immersion in disinfectant solution.

1. Clean the outside surfaces with a disinfectant solution.

2. Wipe the outside surfaces with a damp cloth and allow to dry before storing or reusing.

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PREDICATE LITERATURE

DYONICS

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Smith & Nephew Dyoni

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Smith+Nephe

Leadership in Worldwide Healthc

160 Dascomb Road, Andover, MA 01810 U.S
Telephone: 508-470-2800 Fax: 508-470-21

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3500 - PS3500EP Arthroscopic Surgical System **$10,000**

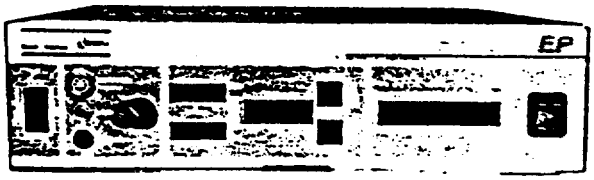
CONTAINS ONE EACH

3478	PS3500EP Control Unit 120V
3476	PS3500EP Motor Drive
3498	Footswitch
4323	Sterilization Tray

3550 - PS3500EP Arthroscopic Surgical System Plus **$15,000**

CONTAINS ONE EACH

3478	PS3500EP Control Unit 120V
3476	PS3500EP Motor Drive
3498	Footswitch
4323	Sterilization Tray
3391	Mini Motor Drive



3478 **$4,200**
PS3500EP Control Unit 120V

3476 **$5,900**
PS3500EP Motor Drive

For Smith & Nephew Dyonics Customer Service
Please Call 1-800-343-5717

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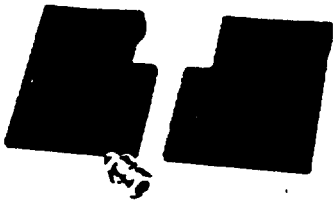
3391 **$5,800**
Mini Motor Drive Unit

3498 **$485**
Footswitch - New Version with Wider Foot Pedals



4521 **$75**
Footswitch Upgrade Package - Wider Foot Pedals

4323 **$300**
Sterilization Tray

4324 **$150**
Insert for 4323 Tray

Questions or Comments Email CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

3406 - Mini Arthroscopic Surgical System **$9,400**

CONTAINS ONE EACH:

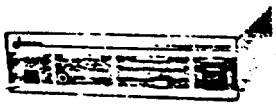
3385	Control Unit
3391	Mini - Motor Drive Unit
4323	Sterilization Tray
1990	Footswitch
3392	Replacement Power Cord

3580 - PS3500EP Mini Arthroscopic Surgical System **$10,000**

CONTAINS ONE EACH:

3478	PS3500EP Control Unit
3391	Mini - Motor Drive Unit
4323	Sterilization Tray
3498	Footswitch, Three-Mode, 12-foot Cord
3392	Replacement Power Cord

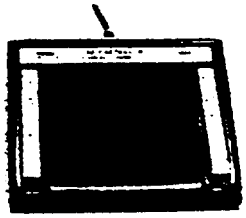
◆ REPLACEMENT PARTS



3385 **$3,450**
Mini Control Unit

3391 **$5,800**
Mini Motor Drive Unit

3392 **$430**
Replacement Power Cord



1990 **$470**
Footswitch, Two-mode, 8-ft Cord, for Model 85 and Mini

4323 **$300**
Sterilization Tray

◆ ACCESSORIES

3413 **$125/box**
Small Joint Inflow Set, 10 per Box

3427 - Operative Instrument Set, 2.2mm **$450**

INCLUDES:

CAT. #:	DESCRIPTION:
3214	Cannula, 2.2mm
3216	Obturator, 2.2mm
3215	Trocar, 2.2mm
3312	TMJ /Wrist Probe

3428 **$300**
2.0mm Golden Retriever

3312 **$105**
Wrist Probe

For Smith & Nephew Dyonics Customer Service
Please Call 1-800-343-5717

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PREDICATE LITERATURE

KARL STORZ

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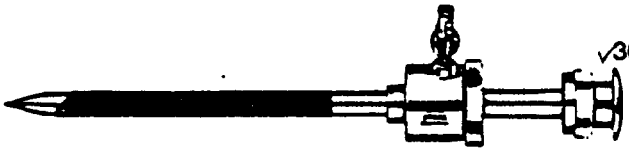
Trocars, size 9 mm and Thread Sleeve

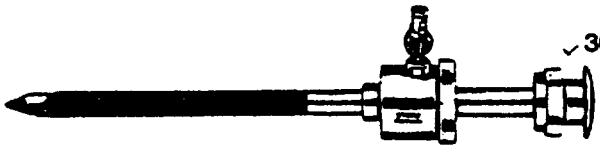
Color code: blue.

KARL STORZ — ENDOSKOP

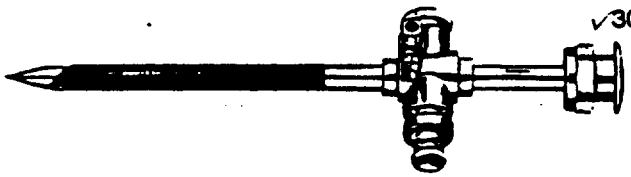
Multiple Puncture Approach.



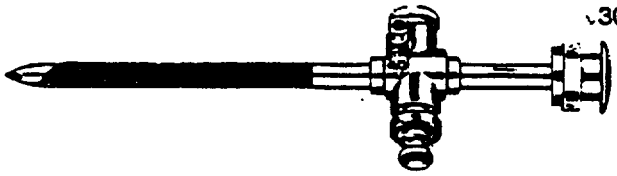
30102 KC **Trocar**, consisting of:
- 30102 C Trocar only, with conical tip.
- 30102 K Cannula with automatic valve, insufflation stopcock, length 10.5 cm.



30102 KP **Trocar**, consisting of:
- 30102 P Trocar only, with pyramidal tip.
- 30102 K Cannula with automatic valve, insufflation stopcock, length 10.5 cm.



30102 TC **Trocar**, consisting of:
- 30102 C Trocar only, with conical tip.
- 30102 T Cannula with trumpet valve, insufflation stopcock, length 10.5 cm.



30102 TP **Trocar**, consisting of:
- 30102 P Trocar only, with pyramidal tip.
- 30102 T Cannula with trumpet valve, insufflation stopcock, length 10.5 cm.

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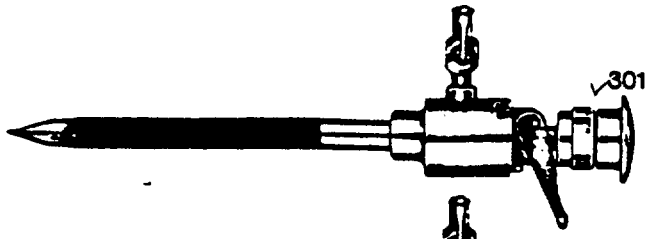
Trocars, size 11 mm and Thread Sleeve

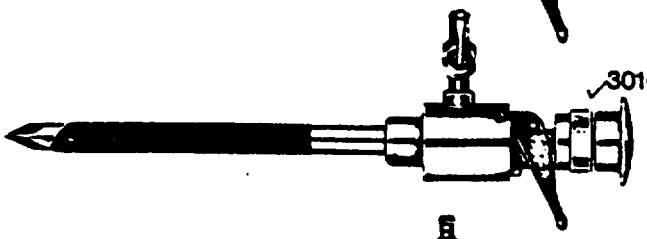
Color code: green.

STORZ
KARL STORZ — ENDOSKOPE

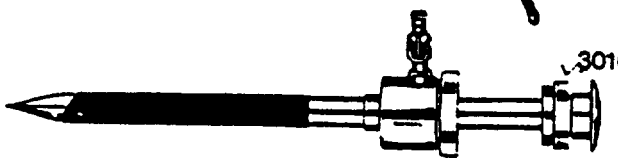
Multiple Puncture Approach.



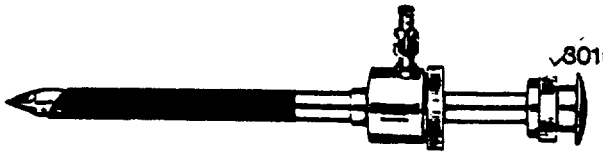
30103 MC **Trocar**, consisting of:
- 30103 C Trocar only, with conical tip.
- 30103 M Cannula with multifunctional valve, insufflation stopcock, length 10.5 cm.



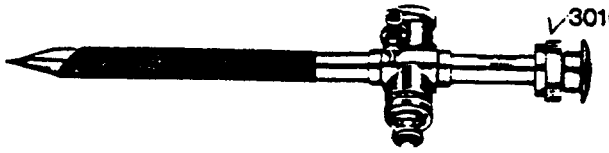
30103 MP **Trocar**, consisting of:
- 30103 P Trocar only, with pyramidal tip.
- 30103 M Cannula with multifunctional valve, insufflation stopcock, length 10.5 cm.



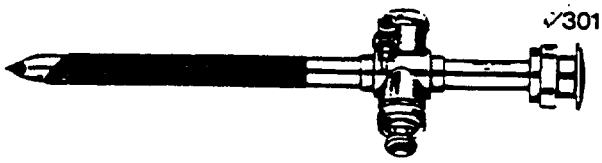
30103 KC **Trocar**, consisting of:
- 30103 C Trocar only, with conical tip.
- 30103 K Cannula with automatic valve, insufflation stopcock, length 10.5 cm.



30103 KP **Trocar**, consisting of:
- 30103 P Trocar only, with pyramidal tip.
- 30103 K Cannula with automatic valve, insufflation stopcock, length 10.5 cm.



30103 TC **Trocar**, consisting of:
- 30103 C Trocar only, with conical tip.
- 30103 T Cannula with trumpet valve, insufflation stopcock, length 10.5 cm.



30103 TP **Trocar**, consisting of:
- 30103 P Trocar only, with pyramidal tip.
- 30103 T Cannula with trumpet valve, insufflation stopcock, length 10.5 cm.

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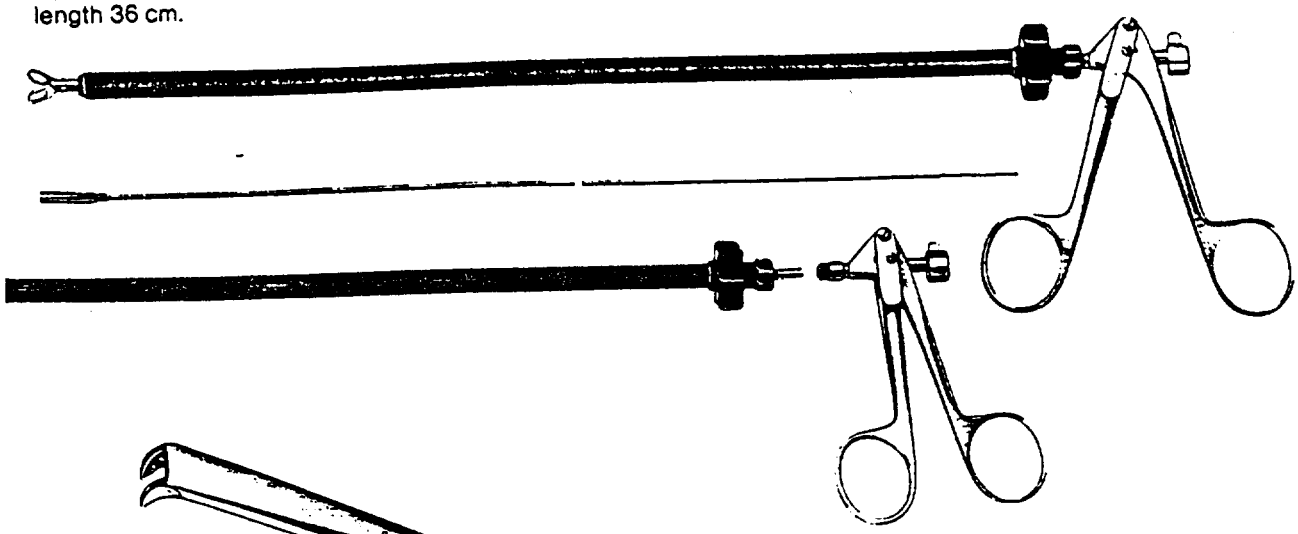
STORZ
KARL STORZ — ENDOSKOPE

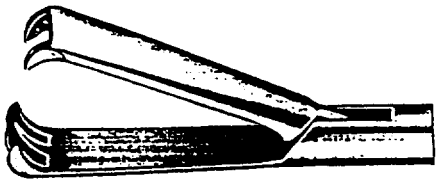
Dissecting and Grasping Forceps

take-apart® – rotating,

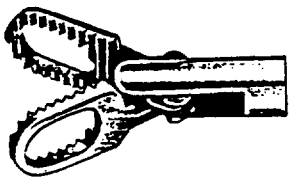
'thout Insulation, size 10 mm.

Multiple Puncture Approach.
Operating instruments for use with trocar size 11 mm, length 36 cm.





30422 FS **Take-apart®, rotating Claw Forceps,**
single action jaws,
consisting of:
30552 **Metal Handle,** with ratchet.
30540 **Outer Tube.**
30420 FS **Insert, Claw Forceps.**



30422 TH **Take-apart®, rotating Grasping Forceps,**
double action jaws,
consisting of:
30552 **Metal Handle,** with ratchet.
30540 **Outer Tube.**
30420 TH **Insert Grasping Forceps.**

280080 **Brush for Cleaning,** autoclavable,
package of 5.

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STERILIZATION AND CLEANING

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CLEANING AND STERILIZATION INFORMATION FOR KARL STORZ ENDOSCOPIC INSTRUMENTS

I. CLEANING

Proper care and maintenance of surgical instruments requires complete disassembly and meticulous mechanical cleaning. Careful attention to detail will prolong the useful life of instruments and protect patients from cross-infection.

Prior to any sterilization procedure, all organic matter, blood and irrigation fluid must be removed. Use a liquid detergent with a neutral pH that is designed for use with surgical instruments. Powdered soaps may leave deposits that can cause corrosion or interfere with moving parts. Distilled or demineralized water is recommended for cleaning, as saline or mineral deposits in tap water may pit or corrode the instruments.

Instruments which have been used with dextran should be completely disassembled immediately after a procedure, placed in very hot water for at least 5 minutes and meticulously cleaned. This cleaning procedure is essential or residual dextran will solidify as it dries. If dextran has not been completely removed and the moving parts of the instrument do not function on the sterile field, running them through a steam autoclave cycle or dipping them in very hot or boiling water may liquefy the dextran. This will allow the instruments to be used for the scheduled procedure. If several procedures are scheduled back to back, soaking and cleaning with very hot water between cases is still essential. Dextran will adhere to instruments if it is not removed BEFORE sterilization.

When cleaning, avoid using abrasive materials. Use soft cloths or scrub brushes, toothbrushes and cotton tip applicators to remove residual organic matter, blood or irrigation fluid. Proper contact of the sterilization medium to the instruments will occur only if the instruments are clean. Steam will penetrate residual organic matter, but the residue that will be left after sterilization may subsequently affect operation of the instruments.

Thorough rinsing of instruments with distilled, demineralized or tap water is essential. Dry thoroughly. Cleaning pistols which attach to water or air are useful time-saving tools for both rinsing and drying.

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II. LUBRICATION

All moving parts should be lubricated to prevent "freezing" of stopcocks, forcep jaws and other moving parts. Instruments that have been in contact with dextran may benefit from soaking in an instrument milk bath. A water soluble lubricant can penetrate into moving parts and may help counteract the effects of any residual dextran solution.

Prior to sterilization, some instruments can be partially reassembled. However, tight locking mechanisms (e.g., washer assemblers, trap door valves) and channel caps should not be reassembled, since this might interfere with sterilization

III. STERILIZATION

In order to achieve the desired standard assurance level (SAL) of 10^{-6}, we recommend steam and EtO sterilization methods. Sterilize as often as needed and/or desired. **Do not sterilize or disinfect the connecting cord in antiseptic solutions**. Discard the device if it is cracked, bent, tarnished or otherwise damaged.

A. Steam Sterilization

(b)(4)

[redacted]

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III. STERILIZATION (continued)

B. Ethylene Oxide Sterilization (EtO)

(b)(4)

[redacted]

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SCIENTIFIC JOURNAL ARTICLES

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ELECTRICAL CUTTING DEVICE FOR LAPAROSCOPIC REMOVAL OF TISSUE FROM THE ABDOMINAL CAVITY

Rolf A. Steiner, MD, Edward Wight, MD, Yona Tadir, MD, and Urs Haller, MD

The extraction of large tissue masses from the abdominal cavity during laparoscopic surgery is a time-consuming, complicated process. A new prototype instrument is introduced that allows quick laparoscopic removal of fibromas, ovaries, or other tissues from the abdomen. A cylinder with a coning knife at its intra-abdominal end is placed inside the trocar sleeve and is rotated by an electrical micro-engine attached to the trocar. Cylindrical tissue blocks are cut step by step out of the main specimen and removed from the peritoneal cavity through the sleeve with a grasping forceps. Tissue removed is suitable for histologic examination. The principal application is morcellation of fibromas, whereas use in ovarian disease is limited. This new device provides a safe and effective approach inside the abdominal cavity. *(Obstet Gynecol 1993;81:471–4)*

From the Departement für Frauenheilkunde, Universitätsspital Zürich, Zürich, Switzerland; and Beckman Laser Institute & Medical Clinic, University of California, Irvine, California.

Construction was supported by J. Anklin AG, Basel, Switzerland, and K. Storz GmbH & Co., Tuttlingen, Germany.

Laparoscopic surgery has become increasingly popular because it offers minimal traumatic effect on the tissue, fewer postoperative complications, shorter convalescence, and better cosmetic results.[1,2] A major problem during laparoscopic operations is removal of large

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2. Nezhat CR, Nezhat FR, Metzger DA, Luciano AA. Adhesion reformation after reproductive surgery by videolaseroscopy. Fertil Steril 1990;53:1008–11.
3. Semm K. Tissue-puncher and loop ligation—new aid for surgical-therapeutic pelviscopy (laparoscopy) endoscopic intraabdominal surgery. Endoscopy 1978;10:119–24.
4. Semm K. Morcellement and suturing using pelviscopy—not a problem any more. Geburtshilfe Frauenheilkd 1991;51:843–6.

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Minimally Invasive Surgery

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MINIMALLY INVASIVE SURGERY

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ESSENTIALS OF

Laparoscopy

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Boston, Massachusetts

1994

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SUMMARY OF SAFETY AND EFFECTIVENESS

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Toll Free 800 421 0383
Fax 310 410 5527

SUMMARY OF SAFETY AND EFFECTIVENESS

The Karl Storz Steiner Electromechanic Morcellator and the predicate devices are motorized surgical devices which morcellate and remove tissue from the surgical site. These instruments are designed for use by qualified surgeons during urology endoscopic procedures.

The device comes into contact with the human body for brief periods of time. The body contact material is commonly used in medical devices for a wide range of applications, and has a long history of biocompatibility for human use.

The Karl Storz Steiner Electromechanic Morcellator is substantially equivalent to the predicate devices since the basic features, design, and intended uses are the same. The minor differences in design and dimensions between the Karl Storz Steiner Electromechanic Morcellator and accessories and the predicate devices raise no new issues of safety and effectiveness as these design differences have no effect on the performance, function, or intended use of the devices.

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