



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)
FOLDER: K020732 - 66 pages
COMPANY: COOK BIOTECH, INC. (COOKBIOT)
PRODUCT: DRESSING, WOUND, COLLAGEN (KGN)
SUMMARY: Product: SS MATRIX

DATE REQUESTED: Aug 1, 2016

DATE PRINTED: Aug 1, 2016

Note: Printed



9. 510(K) SUMMARY

MAY 30 2002

Submitted By:

Mark Bleyer
President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355

February 26, 2002

Device:

Trade Name:	SS Matrix™
Common/Usual Name:	Topical Wound Dressing
Proposed Classification Name:	Liquid bandage; 21 CFR 880.5090; Class I
	Product Code: 79KMF

Intended Use:

The SS Matrix™ is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds. The device is intended for one-time use.

Predicate Devices:

The SS Matrix™ is similar to predicate collagen-based wound dressings that are currently marketed for the management of wounds including the SIS Wound Dressing II (D.C. #K993948) manufactured by Cook Biotech Incorporated, the FIBRACOL* Plus Collagen Wound Dressing (D.C. #K982597) manufactured by Johnson & Johnson Medical, and the EZ Derm™ Biosynthetic Wound Dressing (D.C. #K935189) manufactured by Brennen Medical Incorporated.

Device Description:

The SS Matrix™ is primarily composed of porcine collagen that is supplied in sheet form in sizes ranging from 2 x 4 cm to 20 x 40 cm.

Substantial Equivalence:

The SS Matrix™ is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalence.

Discussion of Tests and Test Results:

The SS Matrix™ was subjected to a panel of tests to assess biocompatibility. The SS Matrix™ passed the requirements of all tests.

Conclusions Drawn from Tests:

This device is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2002

Mr. Mark Bleyer
President
Cook Biotech, Inc.
3055 Kent Avenue
West Lafayette, IN 47906

Re: K020732
Trade/Device Name: SS Matrix
Regulatory Class: unclassified
Product Code: KGN
Dated: March 5, 2002
Received: March 6, 2002

Dear Mr. Bleyer:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

Page 2 – Mr. Mark Bleyer

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020732Device Name: SS Matrix™

Indications For Use:

The SS Matrix is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Draining wounds.

The device is intended for one-time use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Miriam C. Probst***(Division Sign-Off)**Division of General, Restorative
and Neurological Devices510(k) Number K020732

Prescription Use

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

(Optional Format 1-2-96)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2002

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President
Cook Biotech, Inc.
3055 Kent Avenue
West Lafayette, IN 47906

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Regulatory Class: unclassified
Product Code: KGN
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Sincerely yours,

Miriam C. Probst
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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- Draining wounds.

The device is intended for one-time use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices510(k) Number K020732

Prescription Use _____

OR

Over-The-Counter Use 3

(Per 21 CFR 801.109)

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

(Optional Format 1-2-96)

5/17/02

DXK Memorandum

Reviewer(s) - Name(s) David Berkowitz

Subject: 510(k) Number K020732

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

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

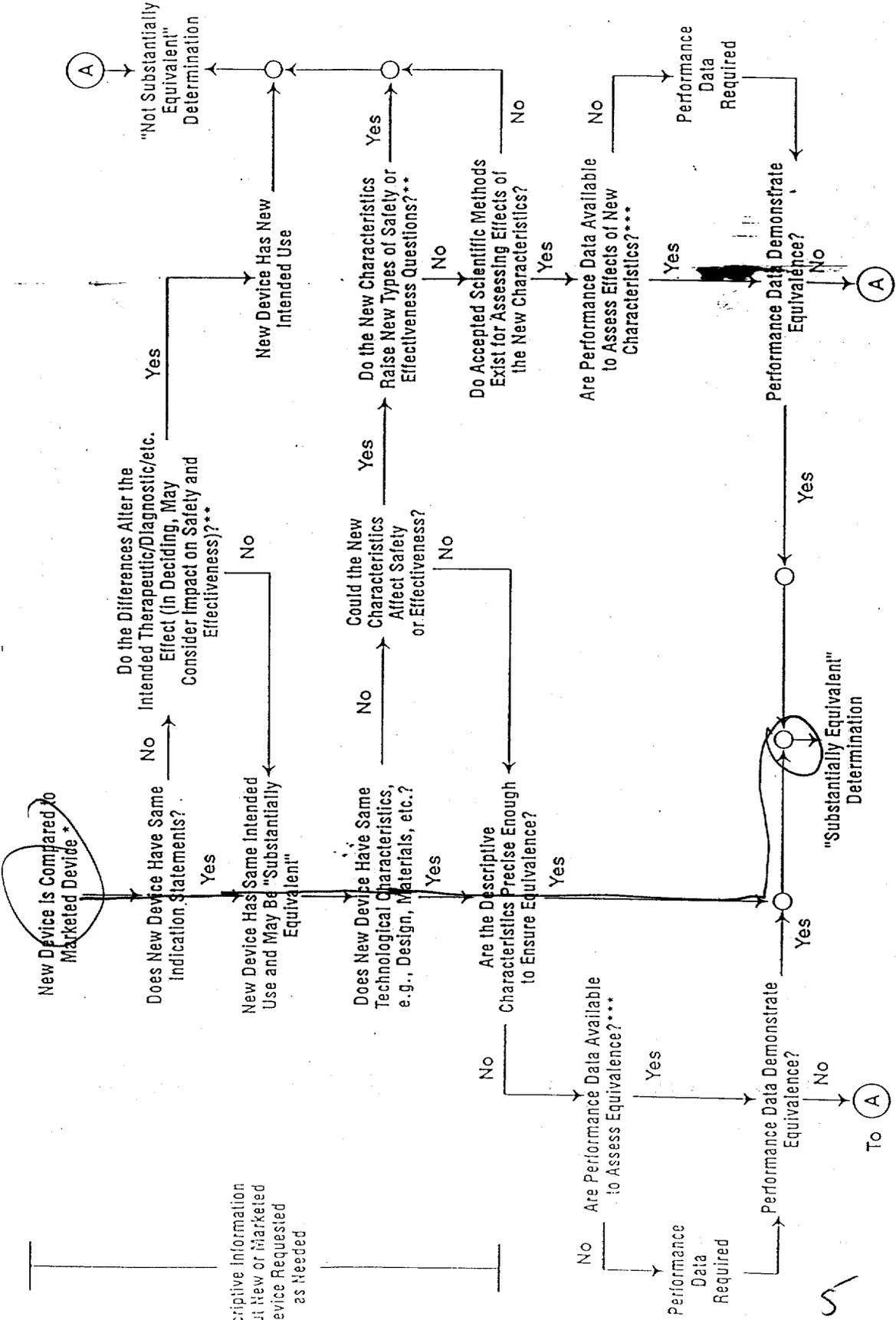
KG-N Popping Dressing Unclassified (with animal product)

Review: Steph Rhodes PRS 5/29/02
(Branch Chief) (Branch Code) (Date)

Final Review: Miriam C. Provost 5/30/02
for (Division Director) (Date)

Revised: 8/17/99

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.

510 (K) MEMORANDUM

TO: File

FROM: David B. Berkowitz, Reviewer
ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

DATE: May 15, 2002

SUBJ: **K020732**
SS Matrix
Cook Biotech Incorporated
Mark Bleyer, President 765 497-3355

Recommendation:

Procode: KGN

~~Class: Class II~~

Regulation Number: Unclassified, Porcine Dressing

REVIEW:

1. Does the product contain drugs or biologicals? If yes, what is the drug/biologic.

This is a porcine dressing made from the swine stomach. The muscle and mucosal layers are removed, and what remains is disinfected.

2. Indication and/or Intended Use Statement

Subject Device

Partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, Tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears), draining wounds.

Predicate Devices

SIS Wound dressing II K993948 KMF hydrophilic wound dressing.

T

The indications are identical to the current dressing.

Fabricol Plus Collagen wound dressing K982597 KMF

Has many, but not all of the above indications.

EZ DERM K935189 KGN – porcine wound dressing

Temporary wound dressing on partial thickness burns and for coverage of donor sites.

Discussion of equivalency

The predicates have the above indications. Tunneled wounds are particularly egregious, because they are more subject to infections, especially anaerobic infections.

3. Technological Characteristics (Design, Materials, Sizes, etc.)

Subject Device – Made of the fibrous components of pig stomach.

Predicate Device(s)

SIS Wound dressing II K993948 KMF hydrophilic wound dressing made of fibrous components of porcine small intestine.

Fabricol Plus Collagen wound dressing K982597 KMF

This dressing contains bovine collagen and calcium alginate. The 2 polymers are crosslinked.

Discussion of equivalency

I believe the fibrous components of swine stomach and bovine intestine are likely to be qualitatively similar. Yields may vary.

4. Comparative Performance Data (in vitro, animal and/or clinical)

Safety Data

Subject Device

Biocompatibility is provided in a master file from NAMSA, MAF-1172. This arrived in January 2002, and is not yet on image. I borrowed the relevant volume from Victoria Scharf in the Document Control Center.

In all the testing, the test article is identified as “STERILE SS.” It is not clear which dressing this is. However, the lot numbers given are P101778 and P101779.

7

Hemolysis – Based on volume of (b) (4) [redacted]
(b) (4) [redacted]

Cytotoxicity – Used [redacted] (b) (4) [redacted]

For a dressing containing a drug or antibiotic, I would insist that the dressing be put directly onto an agar overlay. The use of an extract is satisfactory for a standard type dressing, such as this one.

Intracutaneous reactivity – Sterile SS extracted into saline at ratio above. Solutions were injected intracutaneously (b) (4) [redacted] in rabbits. The skin was observe for erythema and edema at 24, 48, and 72 hours post injection. Neither the extract with suspended particles nor the clear extract caused irritation.

Primary skin irritation – The dressing was cut into (b) (4) [redacted]
(b) (4) [redacted]

Acute Systemic Toxicity – Test article extracted into sodium chloride in usual ratio. (b) (4) [redacted]
[redacted]

Sensitization assay was provided by facsimile transmission and was added to the document. The extracts tested were neither irritating or sensitizing.

Predicate Devices

K993948 – SIS Wound Dressing II – intestinal collagen.
Testing was similar to the current battery, but included pyrogenicity, muscle implantation, and subchronic systemic toxicity.

K982597 – Fabracol – GP maximization test, skin irritation, cytotoxicity, subchronic toxicity. This dressing was severely cytotoxic.

**Effectiveness Data
Subject Device**

None

**Predicate Device(s)
Test methods and results**

None

Discussion of Equivalency

The testing was similar in the test and predicate dressings.

5. Sterilization

Method – Ethylene Oxide

Validation – ANSI/AAMI/ISO 11135/EN550

Dose - Not applicable

Sterility Assurance Level – 10^{-6}

Residuals will not exceed 20 mg ethylene oxide, 12 mg ethylene chlorohydrin.

Packaging – Polyester-polyethylene film/Tyvek paper pouch.

Pyrogenicity claims – No claims

The sponsor addressed the endogenous animal virus issue by reference to the European Committee for Standardization document, prEN12442-3:1996, Animal Tissues and their derivatives utilized in the manufacture of medical devices. – Part 3: Validation of the elimination of and/or inactivation of viruses and other transmissible agents. The SAL will be at least 10^{-6} . They assumed the viral load of the current product is about the same as the viral load of the predicate SIS product. The predicate material is obtained from small intestine and the material for the current product is obtained from stomach. Porcine parvovirus and retroviruses are of concern.

It is not valid to assume that the viral loads will be equivalent. Trichinella, for example, varies widely in the muscles it infects, and even varies from region to region within the diaphragm muscle. Likewise, prions are found in greatly different levels in different nervous tissues, and are found in some muscles but not others. I spoke to the sponsor, Mr. Bleyer, about this. The actual viral load is small, so they spiked at very high levels. The levels of the spike are much higher than would be found in any naturally infected tissue, and these were killed to a validation of 10^{-6} . This is satisfactory. The sponsor provided a facsimile transmission to verify this statement. The statement is attached.

6. Labeling

(OTC and/or Prescription) Prescription

Package Insert (page) 6 Satisfactory.

Carton/Pouch Labels (page) 3

7. Claims

There are no claims.

8. Has sponsor provided all administrative requirements?

- Truthful and Accurate Statement (Page) 2
- 510(k) Summary or Statement (Page) 11
- Indication for Use Page (Page} 1

9. Summary

This is a well-organized regular 510(k), which is adequate except for the issues below.

10. Contact History/Requests for More Information:

5-10-02 10:20 M/L Called Mark Bleyer, President 765 497-3355.

1. Please provide a predicate for "tunneled/undermined wounds" and "draining wounds" or remove these indications.
2. In the biocompatibility testing, what exactly was tested, i.e., what is sterile SS?
Sterile SS is a finished sample of the swine stomach dressing.
3. Please provide sensitization testing.
This was provided by facsimile transmission.

The missing items were provided by facsimile transmission, i.e., the sensitization testing.

Diana B. Behaverty 5/20/02
 Name Date
 Plastic and Reconstructive Surgery Devices Branch

10

Records processed under FOIA 2016-525 Released by CDRH on 8/19/16

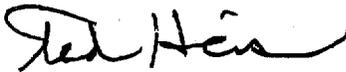
COOK®**MED Institute, Incorporated**
1400 Cumberland Ave.
West Lafayette, IN 47906
Phone: 765 463-7537
Fax: 765 497-0641
www.cookgroup.com**Fax Transmission**Date: May 17, 2002
To: David Berkowitz
Fax: 301-827-4350
From: Theodore Heise, Ph.D., RAC
Number of Pages: cover + 2

Re: Additional information for SS Matrix™

Dear Mr. Berkowitz:

The information requested regarding disinfection validation follows this cover.

Sincerely yours,

Theodore Heise, Ph.D., RAC
Regulatory Scientistcc: Merry Lee Bain, Cook Biotech Incorporated
Mark Bleyer, Cook Biotech Incorporated

CONFIDENTIALITY NOTICE: The materials enclosed with this facsimile transmission are private and confidential and are the property of the sender. The document and the information it contains are privileged and are intended only for the use of the individual(s) or entity(ies) named above. All other use is strictly prohibited. If you are not the intended recipient, be advised that any unauthorized disclosure, copying, distribution or the taking of any action in reliance on the contents of this telecopied information is strictly prohibited. If you have received this facsimile transmission in error, please immediately notify us by telephone to arrange for the return of the forwarded documents.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.US or call 1-800-368-1118

Records processed under FOIA 2016-525 Released by CDRH on 8/19/16

SS Matrix™ Premarket Notification
Response to request for additional information

1

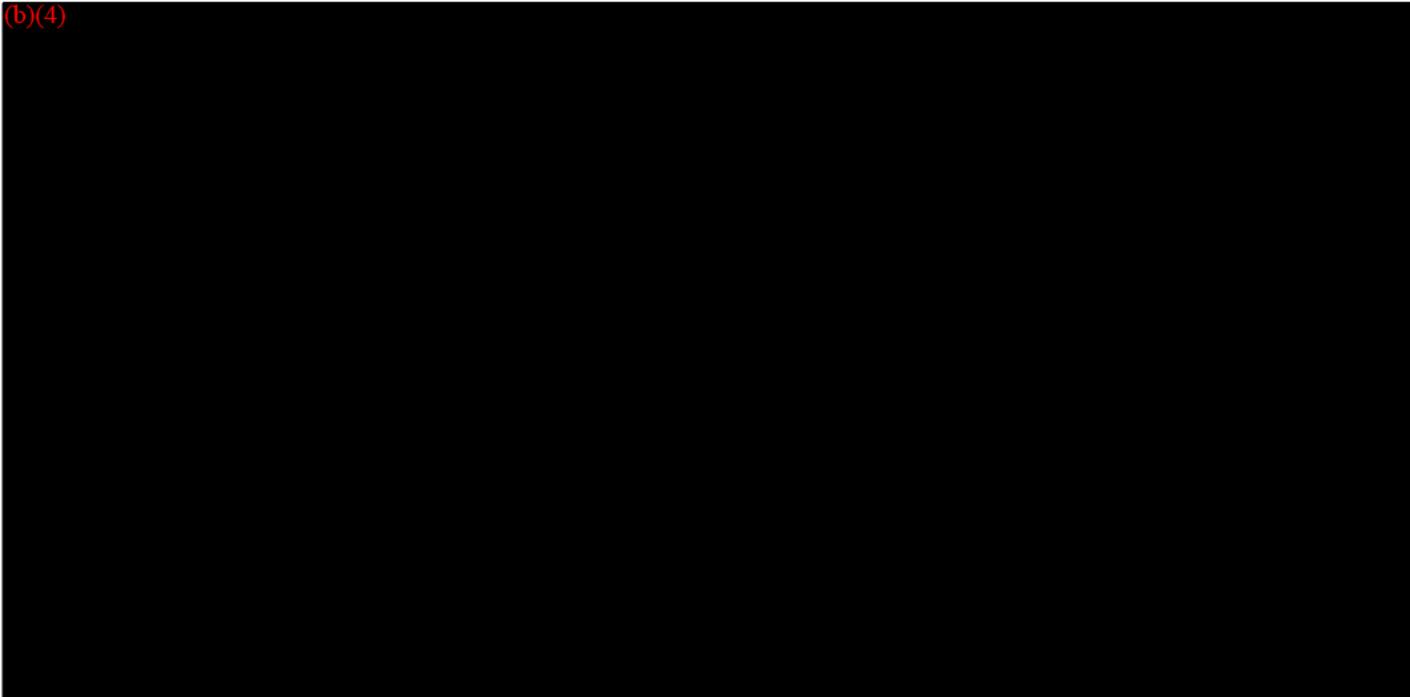
Q.1 Please provide additional information to demonstrate applicability of the validated viral inactivation of SIS (small intestinal submucosa) to the SS Matrix (stomach submucosa) with respect to expected sterility assurance level.

As reported in Sections 1001 and 1002 of the SIS Device Master File MAF-1036 (Vol. I, submitted February 19, 1999), the process for disinfection of SIS (small intestinal submucosa) has been validated for viral inactivation. Two validation studies, based on the methods in European Community Standard prEN12442-3:1996, were conducted in accordance with GLP regulations. In the initial study, two relevant porcine viruses,

(b)(4)

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(b)(4)

A large black rectangular redaction box covers the text following the second paragraph. The text "(b)(4)" is written in red at the top left corner of the redaction.

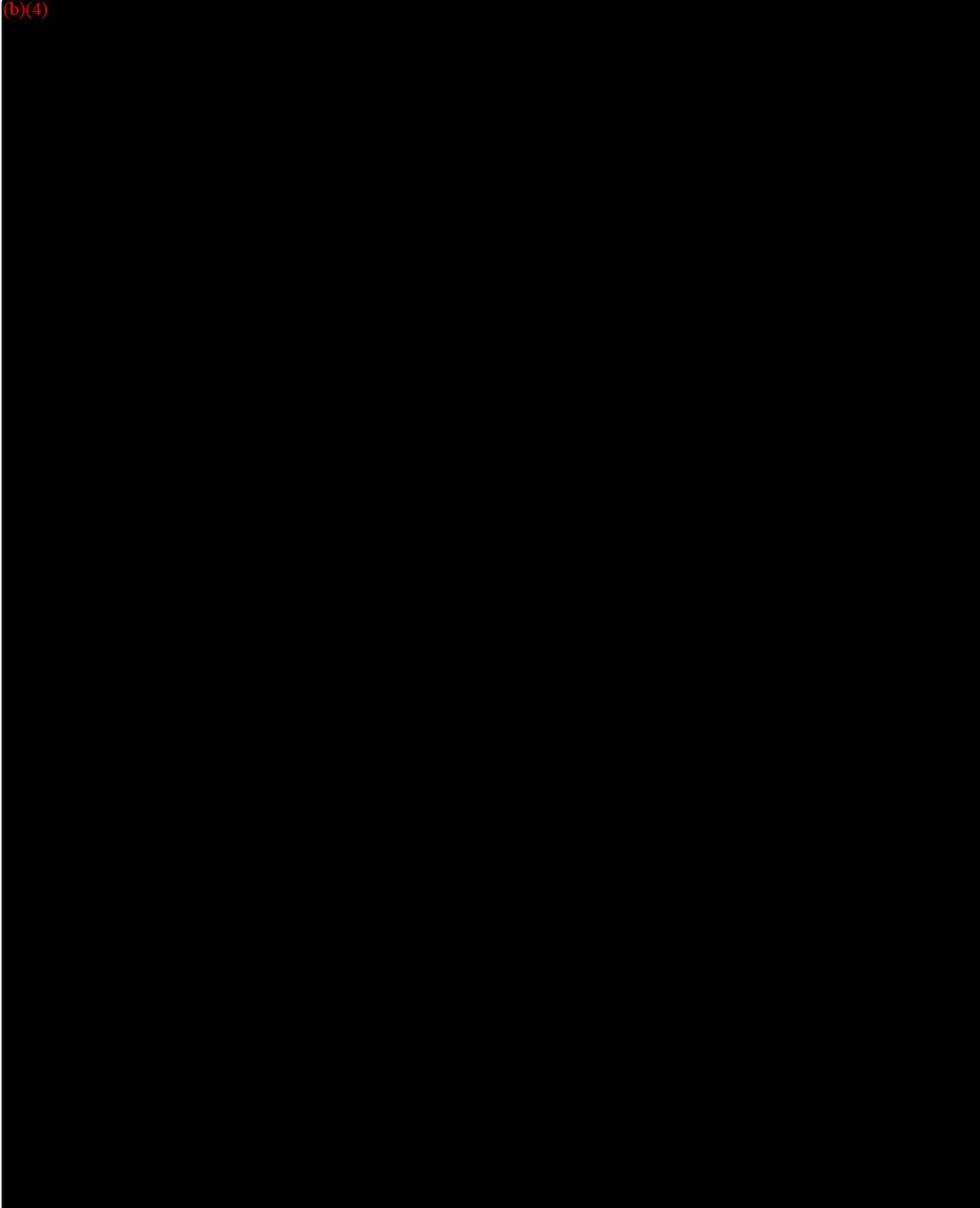
¹ Favero and Bond *Chemical Disinfection of Medical and Surgical Materials* in "Disinfection, Sterilization, and Preservation", 4th Edition; 1991, S.S.Block, Ed.

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Records processed under FOIA 2016-525 Released by CDRH on 8/19/16

SS Matrix™ Premarket Notification
Response to request for additional information

(b)(4)



² Wesley RD, Woods RD, Correa I, and Enjuanes L. Lack of protection in vivo with neutralizing monoclonal antibodies to transmissible gastroenteritis virus. *Veterinary Microbiology* 1988; 18:197-208.

13

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K020732

Reviewer: David Berkowitz

Division/Branch: DGRND/PRSB

Device Name: SS Matrix™

Product To Which Compared (510(K) Number If Known): K993948, K982597

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
5. Same Technological Characteristics?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
9. Accepted Scientific Methods Exist?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Stop NE
10. Performance Data Available?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Request Data
11. Data Demonstrate Equivalence?	<input type="checkbox"/>	<input type="checkbox"/>	Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

See Review Memo

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See Review Memo

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

See Review Memo

510 (K) MEMORANDUM

TO: File

FROM: David B. Berkowitz, Reviewer
ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

DATE: May 15, 2002

SUBJ: **K020732**
SS Matrix
Cook Biotech Incorporated
Mark Bleyer, President 765 497-3355

Recommendation:

Procode: KGN
Class: Class II
Regulation Number: Unclassified, Porcine Dressing

REVIEW:

1. Does the product contain drugs or biologicals? If yes, what is the drug/biologic.

This is a porcine dressing made from the swine stomach. The muscle and mucosal layers are removed, and what remains is disinfected.

2. Indication and/or Intended Use Statement

Subject Device

Partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, Tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears), draining wounds.

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Temporary wound dressing on partial thickness burns and for coverage of donor sites.

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(b)(4)

Cytotoxicity – Used (b)(4)

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Intracutaneous reactivity – Sterile SS extracted into saline at ratio above. (b)(4)

Primary skin irritation – The dressing was cut into (b)(4)

Acute Systemic Toxicity – Test article extracted into (b)(4) (b)(4)

Sensitization assay was provided by facsimile transmission and was added to the document. The extracts tested were neither irritating or sensitizing.

Predicate Devices

K993948 – SIS Wound Dressing II – intestinal collagen. Testing was similar to the current battery, but included pyrogenicity, muscle implantation, and subchronic systemic toxicity.

K982597 – Fabracol – GP maximization test, skin irritation, cytotoxicity, subchronic toxicity. This dressing was severely cytotoxic.

Effectiveness Data
Subject Device

None

Predicate Device(s)
Test methods and results

None

Discussion of Equivalency

The testing was similar in the test and predicate dressings.

5. Sterilization

Method – Ethylene Oxide

Validation – ANSI/AAMI/ISO 11135/EN550

Dose - Not applicable

Sterility Assurance Level – 10^{-6}

Residuals will not exceed 20 mg ethylene oxide, 12 mg ethylene chlorohydrin.

Packaging – Polyester-polyethylene film/Tyvek paper pouch.

Pyrogenicity claims – No claims

6. Labeling

(OTC and/or Prescription) Prescription

Package Insert (page) 6 Satisfactory.

Carton/Pouch Labels (page) 3

7. Claims

There are no claims.

8. Has sponsor provided all administrative requirements?

- Truthful and Accurate Statement (Page) 2
- 510(k) Summary or Statement (Page) 11
- Indication for Use Page (Page) 1

9. Summary

This is a well-organized regular 510(k), which is adequate except for the issues below.

10. Contact History/Requests for More Information:

5-10-02 10:20 M/L Called Mark Bleyer, President 765 497-3355.

1. Please provide a predicate for “tunneled/undermined wounds” and “draining wounds” or remove these indications.

2. In the biocompatibility testing, what exactly was tested, i.e., what is sterile SS?

Sterile SS is a finished sample of the swine stomach dressing.

3. Please provide sensitization testing.

This was provided by facsimile transmission.

The missing items were provided by facsimile transmission, i.e., the sensitization testing.

Name	Date
Plastic and Reconstructive Surgery Devices Branch	

Copy has been set to Stan Brown

Attachment 5

FDA ANIMAL PRODUCTS DATABASE

For each animal derived product device, fill out one DEVICE IDENTIFICATION form.
For each animal product or component in the device, fill out one MATERIAL INFORMATION form

DEVICE IDENTIFICATION INFORMATION

Manufacturer name: Cook Biotech, Inc.
 Submission number: K020732 ODE division DBRND
 Generic Device Name: Porcine Dressing
 Model Identifier or trade name: SS Matrix™
 Implantation or Tissue contact Duration:
 less than 24 hours 24 hours to 30 days greater than 30 days

FROM THE LISTS BELOW, circle the most appropriate:

- generic organ system with which the device makes contact
- tissue with which the device makes contact
- & 4. form of packaging and sterilization used.

ORGAN SYSTEM

- cardiovascular
- dental
- ear
- endocrine
- Gastrointestinal
- musculoskeletal
- neurokological
- ophthalmic
- pulmonary
- reproductive
- soft tissue
- urogenital
- other: Skin - subQ

TISSUE CONTACT

- bladder
- blood
- bone
- brain/CNS
- breast
- gastric
- gingival
- heart
- joint
- kidney
- liver
- lung
- muscle
- ocular
- oral mucosa
- pulmonary
- rectum
- reproductive, female
- reproductive, male
- skin
- subcutaneous
- synovial
- teeth
- vascular
- other:

PACKAGING & STERILIZATION

- bubble wrap
- double blister pack
- foam bubble
- inert gas pack
- single blister pack
- none
- other: Tyvek, polyester-polyethylene

- chlorine dioxide
- dry heat
- electron-beam
- ethylene oxide (ETO)
- filtration
- gamma radiation, in air
- gamma radiation, inert gas
- hydrogen peroxide solution sterilized
- steam
- not sterile
- other:

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MATERIAL AND ANIMAL PRODUCT INFORMATION

Using the tables below, indicate the animal product, species, country of origin, and other indicated information one form for each product or component in the device

TISSUES, CELLS, & BIOMOLECULES (select one)

TISSUES: blood vessel bone cartilage coral cornea dura mater fascia lata fibrous sheath heart valve joint ligament/tendon pericardium umbilical cord umbilical vein viscera other <u>Stomach</u>	BIOMOLECULES: agar albumin alginate BMP cellulose chitosan/chitan chondroitin sulfate collagen elastin fibrin fibrinogen fibronectin gelatin growth hormones heparin hyaluronic acid hydroxypropylmethylcellulose insulin molluscan glue PHB pituitary extract phospholipid polyaminoacid protein extract RGD protein saline serum silk triglycerides, soy bean oil trypsin other _____
CELLS: adipocyte bone marrow chondrocyte endothelial epithelial fibroblast hepatocyte islet keratinocyte osteoblast renal tubular prog. smooth muscle other _____	

SPECIES

bacterial bat bovine (cow) caprine (goat) chicken coral, scleractinia equine (horse) feline (cat) fish fungal/synthetic hamster human, allograft human, self insect kangaroo lapine (rabbit) mollusk monkey murine (mouse) ovine (sheep) plants porcine (pig) rat shark snake

COUNTRY OF ORIGIN?

name: _____

is the material bioresorbable?

yes no

STARTING FORM: was the biological product? (circle one)

purified
 recombinant
 synthetic

FORMING & PROCESSING were any of these processes utilized during fabrication of the component? (circle all that apply)

cell/tissue culture mandrel grown cyropreserved cell seeded TDMAC other _____	cross-linked enzyme treatment fixation, chemical viral inactivation demineralize hydrothermal conversion
--	---

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K020732

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	PA	

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

NA

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

UA

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Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging	NA	
v) specify pyrogen free	NA	
vi) ETO residues	NA	
vii) radiation dose	NA	
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No
 Reviewer: Denise Krane for JPB
 Concurrence by Review Branch: S. Pluch

Date: _____

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

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	NA	
4. If, not, has POS been notified?	✓	
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?		✓
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	NA	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	NA	

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 06, 2002

COOK BIOTECH, INC.
3055 KENT AVE.
WEST LAFAYETTE, IN 47906
ATTN: MARK BLEYER

510(k) Number: K020732
Received: 06-MAR-2002
Product: SS MATRIX

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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC 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. Any telefaxed material must be followed by a hard copy to the DMC (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

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

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K020732

COOK®

Cook Biotech Incorporated

3055 Kent Avenue
West Lafayette, IN 47906
Phone: 765 497-3355
Toll Free: 888 299-4224
Fax: 765 497-2361
www.cookgroup.com

March 5, 2002

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

RECEIVED
MAR 6 10 29 AM '02
FDA/CDRH/OCE/DID

RE: 510(k) Premarket Notification

DEVICE: SS Matrix™

Dear Sir or Madam:

The purpose of this letter is to notify the Food and Drug Administration, pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, that Cook Biotech Incorporated intends to manufacture the SS Matrix™. The SS Matrix™ is similar to the predicate SIS® Wound Dressing II (D.C. #K993948) marketed as OASIS™ Wound Dressing in terms of technological characteristics and intended use. The SS Matrix™ is comprised of porcine stomach submucosa as compared to porcine small intestine submucosa of the SIS Wound Dressing II. See Section 8 of the 510(k) submission for a comparison of the intended uses of the SS Matrix™ to the intended uses of predicate devices.

The following information pertaining to SS Matrix™ is submitted:

1. Trade/Proprietary Name: SS Matrix™
Common/Usual Names: topical wound dressing
2. Establishment Name: Cook Biotech Incorporated
Registration Number: 1835959
3. Proposed Classification: Liquid bandage; 21 CFR 880.5090; Class I
Product Code: 79KMF
4. No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act applicable to this device.
5. A copy of the draft outer package labeling and instructions for use for the SS Matrix™ are shown in Figures 2 and 3 of the 510(k).

SK654/29
/Y

6. The SS Matrix™ is comparable to the following predicate devices. Refer to Section 8 and Exhibit A for product information on these devices.

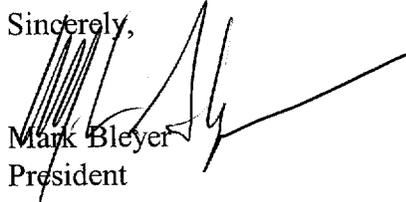
<u>MANUFACTURER</u>	<u>DEVICE</u>
Cook Biotech Incorporated	SIS Wound Dressing II (D.C. #K993948, 79KMF)
Brennen Medical, Inc.	EZ Derm™ Biosynthetic Wound Dressing (D.C. #K935189, 85KNG)
Johnson & Johnson Medical	FIBRACOL* PLUS Collagen Wound Dressing (D.C. #K982597, 79KMF)

7. See Sections 1 through 8 as enclosed for information describing the SS Matrix™ including intended use, device description, packaging and sterilization information, method of use, performance information, and comparison to predicate devices.
8. Refer to Section 9 for a 510(k) summary.

It is hereby certified, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been knowingly omitted.

The intent of Cook Biotech Incorporated to market this device is confidential commercial information. We request that it be considered as such by the FDA and not be available through Freedom of Information except where required by law. Cook Biotech Incorporated requests that the contents of the premarket notification submission be considered as company confidential for an indefinite time period. Unless prior permission from Cook Biotech Incorporated has been obtained, release to the public of any information that has been noted as company confidential will be considered a violation of company rights.

Sincerely,


Mark Bleyer
President

MB:twh
Enclosures

510(k) Number (if known): K02Device Name: SS Matrix™

Indications For Use:

The SS Matrix is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Draining wounds.

The device is intended for one-time use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109) Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(Optional Format 1-2-96)

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1. INTENDED USE

The SS Matrix™ is intended for management of wounds including:

- Partial and full thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunnelled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Draining wounds

The device is intended for one-time use.

2. MATERIALS OF COMPOSITION

The SS Matrix™ is manufactured from porcine stomach wall that has been processed to remove the smooth muscle and mucosa layers and disinfected. The resulting acellular, collagenous, layer is packaged in a lyophilized (dried) state.

The material composition of SS Matrix™ is similar to the predicate SIS Wound Dressing II (DC #K993948), manufactured by Cook Biotech Incorporated, derived from porcine small intestinal submucosa.

3. DEVICE DESCRIPTION/SPECIFICATIONS

The SS Matrix™ is supplied as dried sheets that will be available in sizes ranging from 2 cm by 4 cm to 20 cm by 40 cm, having a nominal thickness ranging from 40 μ m to 400 μ m. The device will be available as a solid sheet or perforated sheet. Refer to Figure 1, which depicts the device.

The SS Matrix™ will be manufactured by Cook Biotech Incorporated, 3055 Kent Avenue, West Lafayette, Indiana, 47906, and will be distributed and marketed by Cook Biotech Incorporated and/or licensee. The source stomach material is derived from animals produced at qualified porcine production facilities. Qualification requirements are equivalent to those for the predicate SIS Wound Dressing II. Please refer to MAF 1036, Section 1011 (Volume 2, submitted March 27, 2001) for additional detail regarding source controls. Throughout manufacturing, trained production and quality control inspectors follow standard procedures, adhering to Good Manufacturing Practices and Quality System Regulations, providing reasonable assurance that the device will perform the intended function with safety and consistency.



Figure 1 Picture of SS Matrix™

4. PACKAGING INFORMATION

SS Matrix™ will be packaged in a polyester-polyethylene film/Tyvek paper pouch which will be sealed and properly labeled. SS Matrix™ can be stored at room temperature. After packaging, the SS Matrix™ is transported for sterilization. Packaging for SS Matrix™ will be equivalent to that for SIS Wound Dressing II, which has been shown to maintain sterility for 18 months. See Figure 2 for a draft package label.

REF: SLO-1-7X10

Quick Reorder # 0

SS matrix

Wound Dressing

7x10 cm

Store at Room Temperature

STERILE EO Sterile if package is unopened or undamaged.

Intended for one-time, single patient use

Read Instructions Prior To Use

00/0000

TB100000



Federal (USA) law restricts this device to sale by or on the order of a physician.

This product is covered by one or more of the following US patents: 6,206,931. Other Patents Pending

Wound Dressing



TB100000

GI-0100

COOK Cook Biotech Incorporated
 3005 Kent Avenue
 West Lafayette, IN 47906
 Toll Free: 888 299-4224

Figure 2 Draft Outer Package Label

5. STERILIZATION INFORMATION

SS Matrix™ will be supplied sterile. SS Matrix™ will be sterilized using an established ethylene oxide (EtO) sterilization cycle that has been validated to a sterility assurance level of 10^{-6} . Sterilization will be performed at Cook Incorporated, 6300 North Matthews Drive, Ellettsville, IN 47929 (establishment registration number 1820334). Sterilization is routinely monitored, calibrated and operated in adherence with specified procedures. The established method used to validate the sterilization cycle is consistent with the half-cycle method as described in ANSI/AAMI/ISO 11135/EN550 *Sterilization of Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization*. Ethylene oxide residuals will be verified below the ISO limits for this type of device, which are 20 mg ethylene oxide and 12 mg ethylene chlorohydrin. After sterilization, EtO-sterilized devices are quarantined pending results of sterility testing. Final product release for distribution is authorized only upon successful completion of sterility testing.

6. METHOD OF OPERATION

The SS Matrix™ is intended for wound management. The wound site should be cleaned thoroughly and all devitalized skin or debris removed. The SS Matrix™ may be applied as is or hydrated prior to use in sterile saline or isotonic solution.

To apply the SS Matrix™, the sheet is cut to a size slightly larger than the outline of the wound area. If the wound is larger than a single sheet, then multiple sheets may be used with adjoining sheets overlapped to provide complete coverage of the wound site. The SS Matrix™ should be aseptically applied to the wound and

smoothed into place ensuring that the sheet is in contact with the underlying wound bed. Following application of the SS Matrix™, the wound site is wrapped with non-adherent outer dressing to maintain a moist wound environment. The optimum secondary dressing is determined by wound location, size, depth, and user preference, and should be changed as needed to maintain a moist, clean wound environment. For additional details, please refer to Figure 3 for draft instructions for use.

COMPANY
CONFIDENTIAL

COMPANY
CONFIDENTIAL

SUGGESTED INSTRUCTIONS FOR USING SS MATRIX WOUND DRESSING

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

NOTE: Always handle SS MATRIX WOUND DRESSING using aseptic technique.

1. Prepare wound area using standard methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue.
2. To apply, cut the dry sheet into a piece slightly larger than the outline of the wound area. If the wound is larger than a single sheet, then multiple sheets may be used. Overlap adjoining sheets to provide coverage of the entire wound. For ease of handling, apply SS MATRIX WOUND DRESSING by placing it in a dry state over the wound and rehydrating the sheet using sterile saline or other isotonic solution. Alternatively, rehydrate the sheet by placing it in a bowl of sterile saline or other isotonic solution for at least one (1) minute prior to use.

3. Place the edge of the sheet in contact with the intact tissue. Smooth SS MATRIX WOUND DRESSING into place to ensure the sheet is in contact with the underlying wound bed.

NOTE: If excess exudate collects under the sheet, small openings can be cut in the sheet to allow the exudate to drain.

IMPORTANT: After application, use an appropriate, non-adherent, secondary dressing to maintain a moist wound environment. The optimum secondary dressing is determined by wound location, size, depth, and user preference. Change the secondary dressing as needed to maintain a moist, clean wound area. Frequency of secondary dressing change will be dependent upon volume of exudate produced and type of dressing used. As healing occurs, sections of SS MATRIX WOUND DRESSING may gradually peel and may be removed during dressing changes. Do not forcibly remove sections of SS MATRIX WOUND DRESSING that may adhere to the wound. Alternatively, the SS MATRIX WOUND DRESSING may form into a caramel-colored gel, which can be rinsed away with gentle irrigation. On inspection, if SS MATRIX WOUND DRESSING is no longer covering the wound, place an additional piece of SS MATRIX WOUND DRESSING over the wound.

INTENDED USE:
SS MATRIX WOUND DRESSING is indicated for the management of wounds including:

- partial and full-thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- tunneled/undermined wounds
- surgical wounds (donor sites/grfts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- draining wounds

SS MATRIX WOUND DRESSING is supplied sterile in peel-open packages and is intended for one-time use.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

CONTRAINDICATIONS: This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material. This device is not indicated for use in third degree burns.

PRECAUTIONS:

- Do not re-sterilize. Discard all open and unused portions of SS MATRIX WOUND DRESSING.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- The device must be used prior to the expiration date.
- Discard device if mishandling has caused possible damage or contamination.
- SS MATRIX WOUND DRESSING should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled.

POTENTIAL COMPLICATIONS: The following complications are possible with the use of wound dressings. If any of these conditions occur, the device should be removed.

- Infection
- Chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation.)
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

STORAGE: This device should be stored in a clean, dry location at room temperature.

STERILIZATION: This device has been sterilized with ethylene oxide.

SS Matrix
WOUND DRESSING
Dry Sheet

FP-0003-1F

COOK

DRAFT

Manufactured for:
Cook Wound/Ostomy Continence
1100 West Morgan Street
P. O. Box 266
Spencer, Indiana 47460 U.S.A.
Phone: 812-829-4891
Toll Free: 800-843-4851
Fax: 812-829-2022
Toll Free Fax: 800-837-4130

Cook Surgical
P.O. Box 489
Bloomington, Indiana 47402 U.S.A.
Phone: 812-339-2235
Toll Free: 1-800-457-4500
Toll Free Fax: 800-554-8335

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Figure 3 Draft Instructions for Use

7. PERFORMANCE INFORMATION

7.1 Biocompatibility

Testing of the SS Matrix™ was performed to support reasonable assurance of biocompatibility. All biocompatibility tests were performed by NAMSA®, 2261 Tracy Road, Northwood, Ohio, 43619 in accordance with the Good Laboratory Practice regulations, 21 CFR Section 58.

Testing included Direct Contact Hemolysis, Cytotoxicity, Acute Intracutaneous Reactivity, Primary Skin Irritation, and Acute Systemic Toxicity. Please refer to Section 3000 of the Device Master Files (MAF-1172) for the final test reports provided by NAMSA®. (Please see Exhibit B for a letter from Cook Biotech authorizing access to sections of 3001-3005 of the Device Master File MAF-1172).

Based on the results of the biocompatibility studies, the SS Matrix™ passed the requirements of all tests supporting biocompatibility. A summary of test results is provided in Table 1.

Table 1 Biocompatibility

Test	Result	Reference	Submitted
Direct Contact Hemolysis	Pass	(b) (4)	
Cytotoxicity	Pass		
Acute Intracutaneous Reactivity	Pass		
Primary Skin Irritation	Pass		
Acute Systemic Toxicity	Pass		

7.2 Disinfection

Validation testing was performed, in accordance with the Good Laboratory Practice regulations, 21 CFR Section 58, to validate the inactivation of viral

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contamination during disinfection processing of the predicate SIS material. Test methods were based on the European Committee for Standardization, prEN12442-3:1996, *Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 3: Validation of the elimination and/or inactivation of viruses and other transmissible agents* and demonstrated that the disinfection process reduces viral load to an SAL of at least 10^{-6} . The anticipated viral load of SS Matrix™ is considered to be comparable to that of SIS. The disinfection method used for SS Matrix™ is substantially equivalent to that of the predicate SIS, with exposure to disinfectants equal to or greater than validated parameters. For detailed information about validation of viral inactivation please refer to Sections 1001 and 1002 of the SIS Device Master File MAF-955 (Vol. 1, submitted February 19, 1999). (Please see Exhibit B for a letter from Cook Biotech authorizing access to Sections 1001 and 1002 of the Device Master File MAF-955.)

8. COMPARISON TO PREDICATE DEVICES

The SS Matrix™ is similar to the following predicate devices: SIS Wound Dressing II (D.C. #K993948, found substantially equivalent on 6 January 2000) marketed by Cook Biotech Incorporated; FIBRACOL* PLUS Collagen Wound Dressing (D.C. #K982597, found substantially equivalent on 20 August 1998) marketed by Johnson & Johnson Medical; and the EZ Derm™ Biosynthetic Wound Dressing (D.C. #K935189, found substantially equivalent on 11 July 1994) marketed by Brennen Medical Incorporated. Please see Table 2, which compares characteristics of the SS Matrix™ to these predicate devices and Exhibit A for product information on predicate devices.

In terms of intended use, the SS Matrix™ is similar to SIS Wound Dressing II, FIBRACOL* PLUS, and EZ Derm™ in that all of these devices have the intended use of wound management for partial-thickness wounds, ulcers, abrasions, and donor sites. Like the SIS Wound Dressing II and FIBRACOL* PLUS, SS Matrix™ is also intended for use in full-thickness wounds.

In terms of technological characteristics, the SS Matrix™ is comparable to the predicate devices in that all are composed of animal-derived materials which are composed primarily of collagen. Like SIS Wound Dressing II and EZ Derm™, the SS Matrix™ is porcine derived, while the FIBRACOL* PLUS is bovine derived and includes calcium alginate. The EZ Derm™ collagen is aldehyde cross-linked, while the SS Matrix™, the SIS Wound Dressing II and the FIBRACOL* PLUS collagen are not.

Being similar with respect to indications for use and technology to several predicate devices, the SS Matrix™ meets the requirements for Section 510(k) substantial equivalence.

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Table 2 Comparison with Predicate Devices

MANUFACTURER	Cook Biotech Incorporated	Cook Biotech Incorporated	Johnson & Johnson Medical	Brennen Medical, Inc.
DEVICE NAME (D.C. #)	SS Matrix™ (K02)	SIS Wound Dressing II (K993948)	FIBRACOL* PLUS Collagen Wound Dressing (K982597)	EZ Derm Biosynthetic Wound Dressing (K935189)
INTENDED USE	For management of wounds including: <ul style="list-style-type: none"> ●Partial and full-thickness wounds ●Pressure ulcers ●Venous ulcers ●Chronic vascular ulcers ●Diabetic ulcers ●Tunneled/ undermined wounds ●Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) ●Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) ●Draining wounds 	For management of wounds including: <ul style="list-style-type: none"> ●Partial and full-thickness wounds ●Pressure ulcers ●Venous ulcers ●Chronic vascular ulcers ●Diabetic ulcers ●Tunneled/ undermined wounds ●Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) ●Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) ●Draining wounds 	Indicated for the management of exuding wounds including: <ul style="list-style-type: none"> ●Full-thickness and partial thickness wounds ●Pressure ulcers ●Venous ulcers ●Ulcers caused by mixed vascular etiologies ●Diabetic ulcers ●Second- degree burns ●Donor sites and other bleeding surface wounds ●Abrasions ●Traumatic wounds ●Dehisced surgical incisions 	A porcine derived xenograft that... can be used for partial thickness skin loss injuries. Use of EZ Derm for burns, decubitus and chronic vascular ulcers, abrasions and donor sites, reduces pain and fluid loss.
ANIMAL ORIGIN	Porcine	Porcine	Bovine	Porcine
TISSUE TYPE	Stomach Submucosa	Small Intestinal Submucosa	90% Epidermis and Dermis Collagen	Aldehyde cross-linked
NOMINAL SIZE	2 x 4 cm to 20 x 40 cm	2 x 4 cm to 20 x 40 cm	5 x 5 cm to 10 x 22 cm	5 x 5 cm plus others

9. 510(K) SUMMARY

Submitted By:

Mark Bleyer
President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355

February 26, 2002

Device:

Trade Name: SS Matrix™
Common/Usual Name: Topical Wound Dressing
Proposed Classification Name: Liquid bandage; 21 CFR 880.5090; Class I
Product Code: 79KMF

Intended Use:

The SS Matrix™ is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds. The device is intended for one-time use.

Predicate Devices:

The SS Matrix™ is similar to predicate collagen-based wound dressings that are currently marketed for the management of wounds including the SIS Wound Dressing II (D.C. #K993948) manufactured by Cook Biotech Incorporated, the FIBRACOL* Plus Collagen Wound Dressing (D.C. #K982597) manufactured by Johnson & Johnson Medical, and the EZ Derm™ Biosynthetic Wound Dressing (D.C. #K935189) manufactured by Brennen Medical Incorporated.

Device Description:

The SS Matrix™ is primarily composed of porcine collagen that is supplied in sheet form in sizes ranging from 2 x 4 cm to 20 x 40 cm.

Substantial Equivalence:

The SS Matrix™ is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalence.

Discussion of Tests and Test Results:

The SS Matrix™ was subjected to a panel of tests to assess biocompatibility. The SS Matrix™ passed the requirements of all tests.

Conclusions Drawn from Tests:

This device is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

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Exhibit A

Predicate Devices

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Device Classification Name	BANDAGE, LIQUID
Regulation Number	880.5090
510(k) Number	K993948
Device Name	SIS WOUND DRESSING II
Applicant	COOK BIOTECH, INC. 3055 KENT AVE. WEST LAFAYETTE, IN 47906 1076
Contact	NEAL E FEARNOT
Product Code	KMF
Date Received	11/22/1999
Decision Date	01/06/2000
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary only
SUMMARY/Approval Letter	SUMMARY
Type	Traditional
Reviewed by Third Party	No

(Database Updated January 7, 2002)
[Accessibility](#)

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K982597

510 (k) FIBRACOL* PLUS Collagen Wound Dressing with Alginate

AUG 20 1998

APPENDIX J

510(k) SUMMARY

1. DATE PREPARED

1 July, 1998

2. SUBMITTER

Johnson & Johnson Medical
A Division of Ethicon Inc.
2500 Arbrook Blvd.
P.O. Box 90130
Arlington, TX 76004-3130

3. CONTACT PERSON

Terry James Dagnon
Regulatory Affairs Project Manager
Phone: 817-784-4953
Fax: 817-784-4992 or 817-784-5292

4. NAME OF THE MEDICAL DEVICE

Classification Name:	Dressing, Wound
Common/Usual Name:	Topical wound dressing
Proprietary Name:	FIBRACOL* PLUS Collagen Wound Dressing with Alginate

5. DEVICE CLASSIFICATION

Product Code/Classification Number:	Unclassified
Regulatory Class:	Unclassified

6. STATEMENT OF SUBSTANTIAL EQUIVALENCE

FIBRACOL* PLUS Collagen Wound Dressing with Alginate is substantially equivalent and identical in function to FIBRACOL* Collagen-Alginate Dressing (K925548) manufactured by Johnson & Johnson Medical, and SORBSAN Topical Wound Dressing (K881854 Steriseal) & (K914575 Dow B. Hickam) Distributed by Dow Hickam Pharmaceuticals, Inc.

7. INDICATIONS FOR USE

FIBRACOL* PLUS Dressing is indicated for the management of exuding wounds including:

- Full thickness & partial thickness wounds
- Pressure Ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second-degree burns

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510 (k) FIBRACOL* PLUS Collagen Wound Dressing with Alginate

- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions
- *Precautions:*
FIBRACOL PLUS Dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause. FIBRACOL PLUS Dressing may be used under compression therapy with healthcare professional supervision.
- *Contraindications:*
FIBRACOL PLUS is not indicated for wounds with active vasculitis, third-degree burns, or patients with known sensitivity to collagen or alginates.

8. PHYSICAL DESCRIPTION

FIBRACOL* PLUS Collagen Wound Dressing with Alginate is an advanced wound care device composed of collagen and calcium alginate fibers. FIBRACOL PLUS is twice as absorbent as our traditional FIBRACOL* Dressing. Its unique combination of natural biopolymers created by a patented process combines the structural support of collagen and the gel forming properties of alginates into a sterile, soft, absorbent, conformable topical wound dressing. The dressing is manufactured from bovine collagen and medical grade alginate.

The source of collagen is from bovine hide splits from Australia. The hides are from healthy cattle slaughtered under the supervision of a Government appointed Veterinary Officer and subsequently processed further in a controlled clean room in order to avoid the possibility of bovine spongiform encephalopathy (BSE) contamination. The collagen is linked with the calcium alginate using a patented process.

9. BIOCOMPATIBILITY

FIBRACOL PLUS has been demonstrated to be an acceptable topical wound dressing.

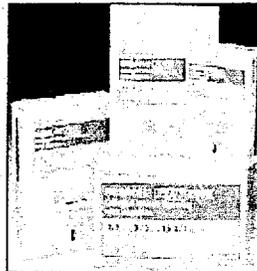
The following safety testing was conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices to support the biocompatibility of this product.

- Agar Overlay Assay (L929 Cells)
- Hemolysis (Rabbit RBCs)
- MEM Elution Test
- Muscle Implantation (Rabbits)
- Systemic Injection (Mice)
- Rabbit Pyrogen Assay
- Primary Skin Irritation (Rabbits)
- Guinea Pig Maximization

In taking all the test results on FIBRACOL PLUS as a whole, FIBRACOL PLUS has been demonstrated to be a safe topical wound dressing in accordance with ISO 10993-1.



- ADVANCED STERILIZATION
- CODMAN
- CORDIS
- DEPUY
- ETHICON (SUTURES)
- ETHICON ENDO-SURGERY
- GYNECARE • WOMEN'S HEALTH
- MEDICAL
- MITEK
- Capillaries/Continuum of Care
- Pack/Clones/Wearing Apparel
- Vascular Access
- Wound Care



Fibracol Plus Collagen Wound Dressing with Alginate

FIBRACOL* PLUS Collagen Wound Dressing has 80% more collagen than traditional FIBRACOL* Dressing. In the presence of wound fluid FIBRACOL* PLUS Collagen Wound Dressing with Alginate maintains a moist microenvironment at the wound surface that is conducive to granulation tissue formation, epithelialization, & enables healing to proceed at a rapid rate.

90% Collagen Composition Easy-to-use

- *Combines with exudate to maintain a moist wound environment, enabling healing to proceed at a rapid rate*
- *Maintains initial integrity when wet*
- *Soft and conformable*
- *Can be customized to fit any size wound*
- *Provides the structural support of collagen*
- *Available in a rope to pack deep wounds*

Non-adherent

- *Helps minimize tissue trauma*
- *Easy to remove*
- *Leaves wound free of fiber*

WHEN TO USE

FIBRACOL* PLUS Collagen Wound Dressing with Alginate is indicated for the management of exuding wounds including:

- Full thickness & partial thickness wounds

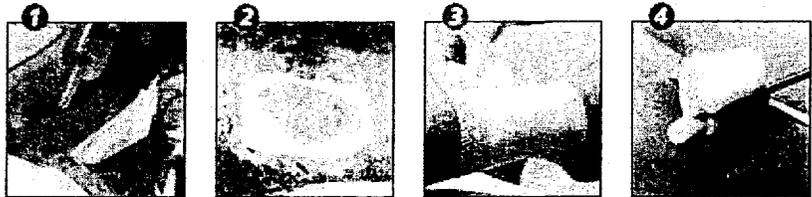
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- Pressure Ulcers
- Venous Ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second-degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions

Precautions: FIBRACOL* PLUS Collagen Wound Dressing with Alginate may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause. FIBRACOL* PLUS Collagen Wound Dressing with Alginate may be used under compression therapy with healthcare professional supervision.

Contraindications: FIBRACOL* PLUS Collagen Wound Dressing with Alginate is not indicated for wounds with active vasculitis, third-degree burns, or on patients with known sensitivity to collagen or alginates.

How to Apply



1. Debride when necessary per facility guidelines and irrigate wound site with normal saline.

2. For heavily exudating wounds, apply to the wound bed directly. Pack deep wounds loosely. For wounds with minimal exudate apply to a moistened wound bed; this will initiate the gel forming process.

3. Cover with appropriate secondary dressing. Secondary dressing selection should be based on the amount of exudate. (BIOCLUSIVE* Transparent Film Dressing for a light amount of exudate or TIELLE* Hydropolymer Dressing, as shown for a more absorbent secondary dressing.)

4. Removal: remove secondary dressing, discard any FIBRACOL* PLUS Collagen Wound Dressing or packing and cleanse with normal saline.

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A heavily draining wound may require daily FIBRACOL* PLUS Collagen Wound Dressing with Alginate changes. Moderately exuding wounds will require less frequent changes (every 2 to 4 days or as directed by a healthcare professional).

FIBRACOL* PLUS Collagen Wound Dressing with Alginate may be used under compression therapy for up to seven days with the supervision of a healthcare professional. As always, follow your facility's treatment protocol with all dressing applications and removals.

- Advanced Wound Care
- TIELLE* Hydropolymer Dressing
- ACTISORB* PLUS
- NU-GEL* Collagen Wound Gel
- NU-GEL* Wound Dressing

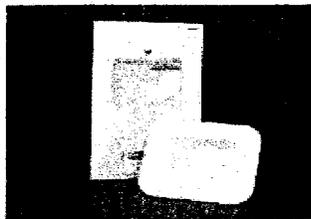
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*Trademark

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Helping the Hands that Heal

FIBRACOL*
Collagen-Alginate
Wound Dressing



REORDER INFORMATION

2494	10 x 11 cm	12/box	6 boxes/case
2495	10 x 22 cm	6/box	6 boxes/case
2496 Rope	1 x 1 x 40 cm	6/box	6 boxes/case
2481	5 x 5 cm	12/box	6 boxes/case
PO 3590	9.5 x 9.5 cm	10/box	1 box/case

A soft, conformable and absorbent topical wound dressing made from a patented process of 90% collagen and 10% alginate. Partial and full-thickness pressure ulcers, venous ulcers, donor sites, dehisced surgical incisions, second degree burns, abrasions and traumatic wounds healing by secondary intention.

- *Collagen compound breaks down gradually*
- *Alginate creates immediate hydrogel*
- *Can be cut to size: multi-layered or rope version*
- *Absorbs up to 78 times its weight*
- *Can fill deep wounds*



Johnson & Johnson
MEDICAL PRODUCTS

*TRADEMARK 1421 LANSDOWNE STREET WEST, PETERBOROUGH,
ONTARIO CANADA K9J 7B9

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Device Classification Name	MONITOR, ULTRASONIC, FETAL
Regulation Number	884.2660
510(k) Number	K935189
Device Name	E-Z DERM BIOSYNTHETIC WOUND DRESSING
Applicant	BRENNEN MEDICAL, INC. 1290 HAMMOND ROAD ST. PAUL, MN 55110
Contact	JEFFREY M WILLIAMS
Product Code	KNG
Date Received	10/26/1993
Decision Date	07/11/1994
Decision	SUBSTANTIALLY EQUIVALENT FOR SOME INDICATIONS (SN)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	General & Plastic Surgery

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Device Classification Name	DRESSING, BURN, PORCINE
510(k) Number	K950032
Device Name	MEDISKIN(R) SS, ZENODERM BIOLOGICAL WOUND DRESSIN
Applicant	BRENNEN MEDICAL, INC. 1290 HAMMOND ROAD ST. PAUL, MN 55110
Contact	THOMAS A DOLD
Product Code	KGN
Date Received	01/04/1995
Decision Date	06/28/1995
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery

FRONT OF ALUMINUM PACKAGE

E•Z DERM™
Nonperforated
Porcine Biosynthetic Wound Dressing

1 UNIT(S) Approximately 2 in x 2 in (5 cm x 5 cm) CE 0080

LOT 9821806 REF E-202

MFG AUG 07 1998 EXP FEB 2000

STERILE R

For single use only 

See instructions 

Store at room temperature. Either side of E•Z DERM™ may be applied to the wound. CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a health care professional. U.S. Patent Nos. 3842831, 4115928.



43271B

4374/A

Manufactured by:
Brennen Medical, Inc.
1390 Hammond Road, St. Paul, MN 55110 U.S.A.
Ph: (612) 429-7413 • (800) 338-9105 • Fax: (612) 429-8020
Authorized Representative: Sander Group B.V.
Tijpsteaan 22, 1119 NZ Schiphol-Boijl, The Netherlands
Ph: (31) 20 653 0553 • Fax: (31) 20 653 3053

Back of package.

E•Z DERM™ Biosynthetic Wound Dressing is a porcine derived xenograft in which the collagen has been crosslinked with an aldehyde.

★ **STORAGE:** E•Z DERM Biosynthetic Wound Dressing can be stored at room temperature. Dressing should not be used after the expiration date. **DO NOT FREEZE.**

APPLICATION: Using aseptic technique at all times to prevent outside contamination of the wound area, thoroughly cleanse and debride the wound of all necrotic tissue, including blisters. Remove the E•Z DERM from the package and apply either side of the dressing to the wound. Use in a single layer, and avoid any wrinkling or creasing of coverage. Overlap adjoining pieces and healthy tissue to provide total wound coverage. Hold the E•Z DERM in place with elastic net dressing or gauze. Perforated dressing allows for normal wound drainage. Inspect the wound daily as excessive fluid accumulation may prevent the dressing from adhering. After the E•Z DERM adheres to the wound, leave it in place until it sloughs. Trim dry, non-adherent E•Z DERM as needed to avoid mechanical dislodgment. The size and quantity of E•Z DERM dressing and the time between dressing changes will vary due to the type of injury being treated, the condition of the wound being covered and the clinical course of the patient.

INDICATIONS: E•Z DERM Biosynthetic Wound Dressing can be used for partial thickness skin loss injuries. Use of E•Z DERM for burns, decubitus and chronic vascular ulcers, abrasions and donor sites, reduces pain and fluid loss. Adherence to the wound site indicates potential acceptance by that site to donor grafts.

CONTRAINDICATIONS: E•Z DERM Biosynthetic Wound Dressing should not be used on patients with known sensitivity to porcine products, on patients with histories of multiple or serious allergies, or on wounds with large amounts of eschar.

PRECAUTIONS: The following precautions should be observed when using E•Z DERM.

1. Covered areas should be inspected daily to detect the formation of any purulent accumulations. Should this occur, remove the dressing, cleanse the area and apply new E•Z DERM.
2. Abrupt temperature elevation is sometimes observed (especially in children) immediately following the application of E•Z DERM. If a high temperature should persist, removal of the dressing is indicated.
3. Any allergic reaction which is unrelated to other therapy is an indication for the removal of E•Z DERM.

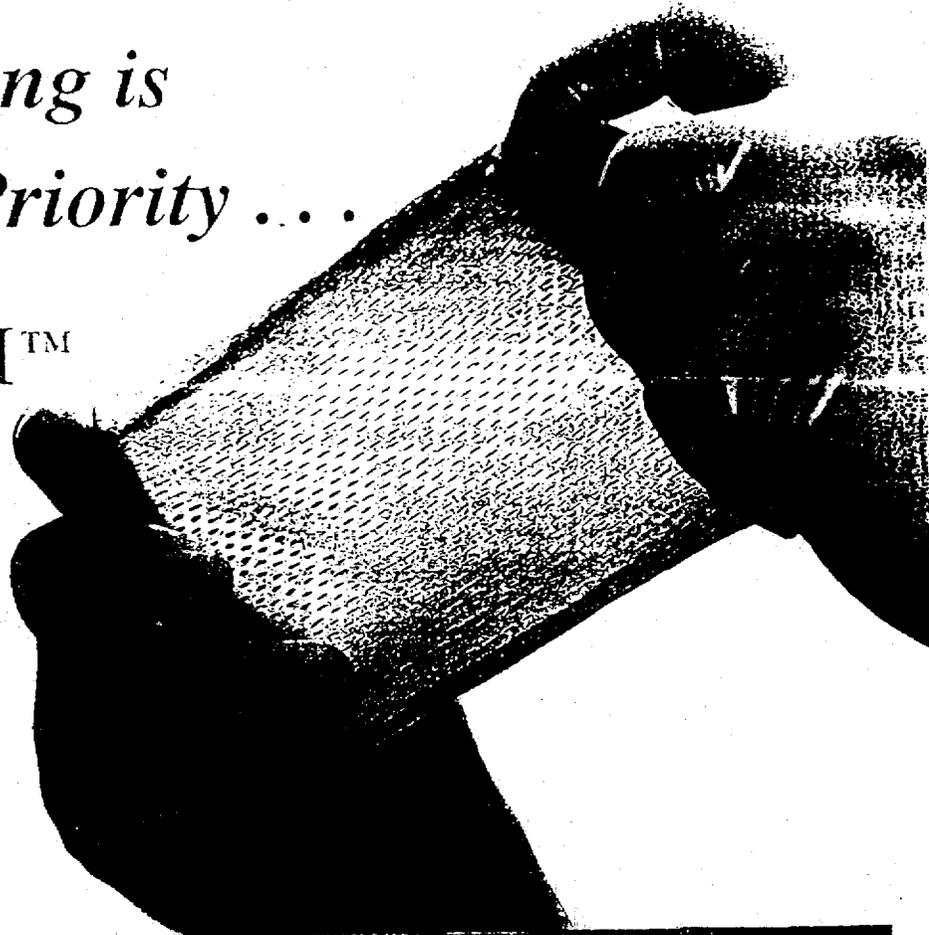
 **MANUFACTURED BY:
BRENNEN MEDICAL, INC.
St. Paul, MN 55110 USA**

4068/C

When Healing is Your First Priority . . .

E•Z DERM™

Biosynthetic Wound Dressing



E•Z DERM™ BIOSYNTHETIC WOUND DRESSING

★ E•Z DERM Biosynthetic Wound Dressing (E•Z Derm) is a porcine derived xenograft in which the collagen has been chemically crosslinked with an aldehyde to provide strength, durability and convenient storage at room temperature. E•Z DERM acts as a temporary protective barrier that allows the natural healing process to continue undisturbed. ★

E•Z DERM is available in a wide variety of sizes, non-perforated* or perforated.*

***E•Z DERM (Non-perforated)—**
For skin loss wounds requiring maximum fluid retention and optimum cosmetic results.

***E•Z DERM (Perforated)—**
For skin loss wounds requiring early exudate management.

**E•Z DERM™
BIOSYNTHETIC WOUND DRESSING**

CROSSLINKING...

...IS STRONGER AND LASTS LONGER

- ◇ All Barms
- ◇ Moist and Ready To Use
- ◇ Patent Complete
- ◇ Cost Effective
- ◇ Room Temperature Storage



Brennen Medical, Inc.
651-429-7413 • 800-328-9105 • 651-429-8020 FAX

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TYPES OF WOUNDS

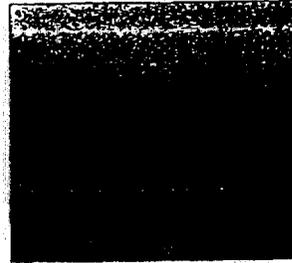
Partial-Thickness Wounds

On clean partial thickness wounds E•Z Derm provides the optimal environment for epithelial regeneration. In most cases, partial thickness wounds will heal beneath the E•Z Derm Dressing in 7-10 days.

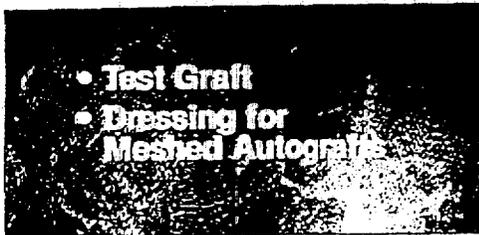


Donor Sites

E•Z Derm offers soothing pain relief on contact and maintains patient comfort during the healing process. The collagen in E•Z Derm provides a natural hemostasis.



Autograft Test Graft—Meshed Autografts

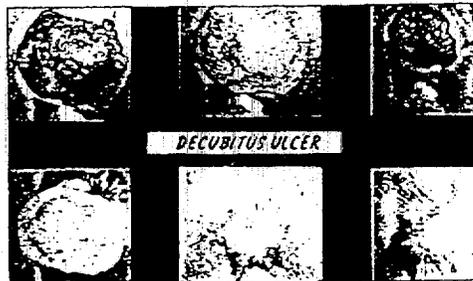


E•Z Derm has been used successfully as a test graft to insure a proper wound bed for autografting and to protect the interstices when used on meshed autografts. When the E•Z Derm Dressing is firmly adhered to the wound and punctate bleeding is noted upon removal of the E•Z

Derm, it is an indication that the wound is clean, healthy and ready for autografting. E•Z Derm will adhere like cadaver skin without the dangers associated with HIV, hepatitis, CMV or other communicable diseases.

Ulcers

Healing by contracture or developing granulation tissue is accomplished by repeated applications of E•Z Derm on even the most difficult cutaneous ulcers. E•Z Derm offers wound protection, pain relief and patient compliance.



Outpatient Treatment

E•Z Derm Dressings for the treatment of skin loss injuries such as abrasions, scalds and avulsions on an outpatient basis has proved to be one of the most cost-effective ways to treat small injuries while providing maximum comfort to the patient.



Wound Protection

- ◆ E•Z Derm Biosynthetic Wound Dressing acts as a temporary protective barrier that allows the natural healing process to continue undisturbed.
- ◆ E•Z Derm keeps body fluids in and bacteria out.
- ◆ Reduces pain by protecting sensitive nerve endings and eliminating painful dressing changes.

Wound Adherence

- ◆ E•Z Derm conforms easily to the wound and allows for undisturbed healing through early adherence.
- ◆ Perforated E•Z Derm allows for exudate drainage while maximizing contact with the wound.
- ◆ Aldehyde crosslinking adds strength and durability for extended wound coverage.
- ◆ Early adherence reduces nursing time and material costs over the course of healing.

Patient Compliance

- ◆ E•Z Derm eliminates painful dressing changes associated with topical creams.
- ◆ Easy outpatient management allows the patient to resume normal activities (bathing/showering) without removing the dressing.
- ◆ Eliminates the danger of communicable diseases associated with human derived tissue.

Convenient

- ◆ E•Z Derm is moist and ready to use.
- ◆ E•Z Derm is shelf-stable.
- ◆ All derms E•Z Derm may be applied either side to the wound.
- ◆ E•Z Derm is available for delivery 24 hours a day, 365 days a week.

EZ DERM™

Biosynthetic Wound Dressing

When Healing is Your First Priority

EZ Derm Biosynthetic Wound Dressing is a porcine derived xenograft in which the collagen has been chemically crosslinked with an aldehyde to provide strength, durability and convenient storage at room temperature.

EZ Derm acts as a temporary barrier that allows the natural healing process to continue undisturbed.

EZ Derm is available in a wide variety of sizes, nonperforated or perforated.

EZ Derm (Non-Perforated) - For skin loss wounds requiring maximum fluid retention and optimal cosmetic results.

EZ Derm (Perforated) - For skin loss wounds requiring early exudate management.

Types Of Wounds

Partial-Thickness Wounds

Donor Sites

Autograft Test Graft – Meshed Autografts

Ulcers

Advantages

Wound Protection

- A. EZ Derm Biosynthetic Wound Dressing acts as a temporary, protective barrier that allows the natural healing process to continue undisturbed.**
- B. EZ Derm keeps body fluids in and bacteria out.**
- C. Reduces pain by protecting sensitive nerve endings and eliminating painful dressing changes.**

Wound Adherence

- A. EZ Derm conforms easily to the wound and allows for undisturbed**

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EZ DERM

Page2

healing through early adherence.

B. Perforated EZ Derm allows for exudate drainage while maximizing contact with the wound.

C. Aldehyde crosslinking adds strength and durability for extended wound coverage.

D. Early adherence reduces nursing time and material costs over the course of healing.

Patient Compliance

A. EZ Derm eliminates painful dressing changes associated with topical creams.

B. Easy outpatient management allows the patient to resume normal activities (bathing/showering) without removing the dressing.

Convenient

A. EZ Derm is moist and ready to use.

B. EZ Derm is shelf storable.

C. EZ Derm is readily available.

Third Party Reimbursement

A. ICD 9 Codes for "Heterograft to skin": Please refer to the book of "International Classification of diseases – 9th revision – Clinical Modifications Procedure Code Number (ICD – 9- CM)".

B. Current Procedure terminology Number (CPT): 15400

C. HCPC code: A4649

For Medical Professional pricing or for more information contact Brennen's Customer Service Department at 1-800-943-4522 or e-mail us at BrennenMedical@worldnet.att.net

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 **Premarket Notification** [Criteria](#) **510(K)** [Listing](#) [MAUDE](#) [TMA](#) [Classification](#)

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Device Classification Name	BANDAGE, LIQUID
Regulation Number	880.5090
510(k) Number	K982597
Device Name	FIBRCOL PLUS COLLAGEN WOUND DRESSING WITH- JOHNSON & JOHNSON MEDICAL, INC.
Applicant	2500 ARBROOK BLVD P.O. BOX 90130 ARLINGTON, TX 76004 3130
Contact	TERRY J DAGNON
Product Code	KMF
Date Received	07/24/1998
Decision Date	08/20/1998
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary only
SUMMARY/Approval Letter	SUMMARY
Type	Traditional
Reviewed by Third Party	No

(Database Updated January 7, 2002)
Accessibility

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Exhibit B

Letter Granting Access to Device Master File

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COOK®

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www.cookgroup.com

February 26, 2002

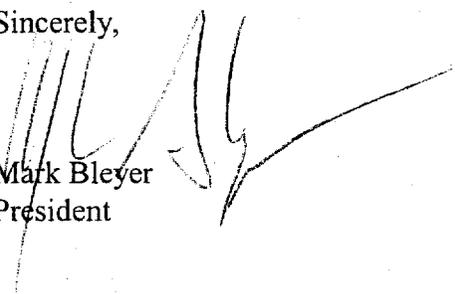
Office of Device Evaluation - 510(k)
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: SS Matrix™

To Whom it May Concern:

This letter hereby authorizes the CDRH, Office of Device Evaluation to incorporate by reference the Device Master Files MAF-1036 (Section 1011), MAF-1172 (Sections 3001-3005), and MAF-955 (Sections 1001-1002) for the purpose of review for substantial equivalence of a premarket notification for the SS Matrix.

Sincerely,


Mark Bleyer
President

MB:tw

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FDA/CDRH IMAGING SYSTEM

Page Count Discrepancy Information

The page behind page 38 was numbered page 36

Verifiers Initials FBA