U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER:	(ixg)
FOLDER:	K061711 - 107 pages (FOI:12003085)
COMPANY:	COOK BIOTECH, INC. (COOKBIOT)
PRODUCT:	DRESSING, WOUND, COLLAGEN (KGN)
SUMMARY:	Product: OASIS WOUND MATRIX
DATE REQUESTED:	Apr 10, 2013
DATE PRINTED:	Apr 10, 2013
Note:	Releasable Version

K061711 1/1

Attachment 4 (Modified 18 July 2006)

SPECIAL 510(K) SUMMARY

JUL 19 2006

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
July 18, 2006

Names of Device:
Trade Name: OASIS® Wound Matrix
Common/Usual Name: Animal-derived, extracellular matrix wound care product
Classification:

Unclassified

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:
The OASIS® Wound Matrix device's intended use is 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 supplied sterile and is intended for one-time use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

Cook Biotech, Inc.
% Mr. Perry W. Guinn
Vice President, Quality Assurance
and Regulatory Affairs
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K061711
Trade/Device Name: Oasis Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 16, 2006
Received: June 19, 2006

Dear Mr. Guinn:

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.

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061711

Indications for Use

510(k) Number (if known): K061711

Device Name: Oasis Wound Matrix

Indications For Use:
The Oasis Wound 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Pruehm for MKM
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K061711

K061711/A1

COOK®

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Phone: 765-497-3355
Toll Free: 888 299-4224
Fax: 765-497-2361
www.cookbiotech.com

Date: 07 July 2006

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

Attention: Peter Hudson

RE: K 061711

Dear Dr. Hudson,

On 05 July, you requested a copy of the Indications for Use in the new FDA format, and; "specifications for the following tests B4 , and B4 In addition, please provide the risk assessment and research opinion that concludes there is no risk to the B4 of the B4 with respect to the B4 ."

In response, I have organized this document into sections, one section per element of your request. I have also added a brief explanation of the material included in each section on the respective section header page. If you need further information, please let me know.

Section 1	New format : Indications For Use
Section 2	B4
Section 3	Physical Properties
Section 4	Risk Assessment
Section 5	B4 Research Opinion

My contact numbers for your convenience are:

Cell Phone	B4
Direct Line	
Switchboard	1.765.497.3355
email	guinn@cookbiotech.com

Please treat this information as Confidential since it contains detailed production specifications that Cook Biotech regards as highly proprietary trade secrets.

K17

Kind regards,

Perry W. Guinn
VP QA/RA

TABLE OF CONTENTS

Addendum to Special 510(k) # K 061711
Response to Peter Hudson's Questions of 05 July 2006

Section 1 New format: Indication For Use

Comment: The new document is printed on the following page.

Indications for Use

510(k) Number (if known): K061711

Device Name: Oasis Wound Matrix

Indications For Use:

The Oasis Wound 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 2 Biological Tests

Comment: The intent of this testing is to determine if the proposed [B4] change has affected the basic nature of the device. No attempt was made to determine the [B4], only that the [B4] had not changed.

These tests were performed per protocols recently published in [B4]. A copy of the Standard is provided at page 6.0 of this document.

The [B4] assessment is intended to measure [B4] that could exist if the product had not been properly [B4]. A passing test is one in which the indicated readings are less than a positive control. All lots of both existing [B4] and [B4] passed the requirement; we therefore conclude that the proposed product is substantially equivalent to the predicate device.

The [B4] is intended to measure the effect of the [B4]. The USP protocol requires [B4] passed the requirement. This is similar to a test of the predicate product done in 2002 on four lots with similar results. We therefore conclude that the proposed device is substantially equivalent to the predicate device.

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

B4 Testing Data and Protocol

Section 3 Physical Properties

Comment: These are the physical or chemical tests done on each production batch. Tests include a B4 [redacted]

These tests, specifications and acceptance criteria have not changed as a result of this B4 [redacted]. The new B4 [redacted] must pass all of the B4 [redacted] inspection and test steps as the predicate product. The tests are confirming and providing evidence that B4 [redacted] has been followed and that the material meets specifications. The tests are also used to B4 [redacted] products.

Relevant CBI Procedures are provided:	Page
CBI Document IW0007O B4 [redacted]	12.0
CBI Document IW0002-1K... B4 [redacted]	13
CBI Document IQ0011N.. B4 [redacted]	14.0

B4 [redacted]

44

12.0

B4 Testing Data

B4 Testing Data

B4 Testing Data

B4 Testing Data

B4 Testing Data

B4 Testing Data

B4 Testing Data

B4 Testing Data

Section 4 Risk Assessment

Comment: Attached is the Process Failure Mode, Effects and Criticality Analysis (PFMECA) for the affected [redacted] The sections regarding [redacted] are on pages numbered 16.8 and 16.9.

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

B4 Risk Assessment Testing Data

Section 5 [redacted] Research Opinion

Comment: [redacted] change can only improve the effectiveness of [redacted]

The full opinion is on the following page.

Cook Biotech Inc.

Memo

To: B4

From: B4

CC: B4

Date: B4

Re: B4

B4

K061711/A3

COOK®

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Phone: 765-497-3355
Toll Free: 888-299-4224
Fax: 765-497-2361
www.cookbiotech.com

July 18, 2006

ATTN: Peter Hudson, Ph.D.
Document Mail Center (HFZ-401)
Office of Device Evaluation – 510(k)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

DEVICE: Oasis® Wound Matrix (D.C. #K061711)
RE: Special 510(k) Summary

Dear Dr. Hudson:

Please receive enclosed the modified Summary (Attachment 4) of the Special 510(k) of the Oasis Wound Matrix. This summary contains revisions to the proposed classification as we have agreed upon. There are three paper copies and one scanned copy of the Summary. Please amend the Special 510(k) accordingly with this information.

If you should have any questions, please call me at B4 [redacted].

Sincerely,

Perry W. Guinn
VP Quality Assurance and Regulatory Affairs

PWG:maf
Enclosures

1 KLS

Attachment 4 (Modified 18 July 2006)

SPECIAL 510(K) SUMMARY

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
July 18, 2006

Names of Device:

Trade Name:	OASIS® Wound Matrix
Common/Usual Name:	Animal-derived, extracellular matrix wound care product
Classification:	Liquid Bandage (KMF) Unclassified

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:

The OASIS® Wound Matrix device's intended use is 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 supplied sterile and is intended for one-time use.

Attachment 4 (Modified 18 July 2006)

SPECIAL 510(K) SUMMARY

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
July 18, 2006

Names of Device:

Trade Name:	OASIS® Wound Matrix
Common/Usual Name:	Animal-derived, extracellular matrix wound care product
Classification:	Liquid Bandage (KMF) Unclassified

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:

The OASIS® Wound Matrix device's intended use is 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),**
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- **draining wounds.**

The device is supplied sterile and is intended for one-time use.

Attachment 4 (Modified 18 July 2006)

SPECIAL 510(K) SUMMARY

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
July 18, 2006

Names of Device:
Trade Name: OASIS® Wound Matrix
Common/Usual Name: Animal-derived, extracellular matrix wound care product
Classification: Liquid Bandage
(KMF)
Unclassified

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:
The OASIS® Wound Matrix device's intended use is 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 supplied sterile and is intended for one-time use.

4

K061711/A005

COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

April 1, 2013

FDA CDRH DMC
APR 02 2013
Received

US Food and Drug Administration
Center for Devices and Radiological Heatlh
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: OASIS Wound Matrix, K061711

B4 [redacted]

Sincerely,

Perry W. Guinn

Perry W. Guinn
VP, Quality Assurance and Regulatory Affairs

PWG:maf
Enclosure

COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

April 1, 2013

US Food and Drug Administration
Center for Devices and Radiological Heatlh
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: OASIS Wound Matrix, K061711

B4 [redacted]

Sincerely,

Perry W. Guinn

Perry W. Guinn
VP, Quality Assurance and Regulatory Affairs

PWG:maf
Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

Cook Biotech, Inc.
% Mr. Perry W. Guinn
Vice President, Quality Assurance
and Regulatory Affairs
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K061711
Trade/Device Name: Oasis Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 16, 2006
Received: June 19, 2006

Dear Mr. Guinn:

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.

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehrn
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061711

Indications for Use

510(k) Number (if known): K061711

Device Name: Oasis Wound Matrix

Indications For Use:
The Oasis Wound 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Pruehs for MKM

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K061711

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

June 19, 2006

COOK BIOTECH, INC.
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906
ATTN: PERRY W. GUINN

510(k) Number: K061711
Received: 19-JUN-2006
Product: OASIS WOUND MATRIX

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see www.fda.gov/cdrh/elecsub.html.

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 one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, 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
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K061711

COOK®

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Phone: 765-497-3355
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Fax: 765-497-2361
www.cookbiotech.com

Date: 16 June 2006

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

K-38

SPECIAL 510(K) DEVICE MODIFICATION

Reference :

Original 510(k)	K993948
Original Trade Name	SIS Wound Dressing II
Current Trade Name	Oasis Wound Matrix (as of 31 May 2002)
Date of Original Concurrence	06 January 2000

Dear Madam/Sir:

Cook Biotech Incorporated hereby submits this **Special 510(k): Device Modification** to request a modification for our Oasis Wound Matrix. The modification is due to a B4 [redacted]. We believe this modification is eligible for the Special 510 (k) process since the modified device has the same fundamental scientific technology and intended use as the predicate device.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at B4 [redacted].

Sincerely,

Perry W. Guinn
Vice President, Quality Assurance & Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
JUN 19 2006
RECEIVED

SY/11

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: B4 [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

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

COOK BIOTECH INC
1425 INNOVATION PLACE
WEST LAFAYETTE IN 47906
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
B4 [redacted]

2. CONTACT NAME
Perry Guinn
2.1 E-MAIL ADDRESS
guinn@cookbiotech.com
2.2 TELEPHONE NUMBER (include Area code)
765-4973355 B4
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

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

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

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
B4 [redacted]

03-May-2006

Form FDA 8601 (08/2003)

71

Special 510 (k) - OASIS Wound Matrix

Table of Contents

COVER SHEET

FDA Document Number_____

Date of Submission: 16 June 2006

Type of Submission: Special 510(k)

Applicant:

Company Name: Cook Biotech Incorporated

Establishment registration Number: 1835959

Phone Number: 765-497-3355

Street Address: 1425 Innovation Place
West Lafayette, IN, USA
47906

Fax Number: 765-497-2361

Contact Name: Perry W. Guinn

Contact Title: VP QA/RA

Contact email: guinn@cookbiotech.com

Contact Direct Phone Number: B4 [redacted]

Alternate Contact: Umesh Patel

Alternate Contact Title: VP Product Development

Alternate Direct Phone Number; B4 [redacted]

Alternate Contact email: patel@cookbiotech.com

COVER SHEET continued

Reason for Submission: Change [redacted]

Product Codes of devices to which substantial equivalence is claimed: KMF

Summary of Safety & Effectiveness data: 510(k) Summary Attached

Information on devices to which substantial equivalence is claimed:

510(k) of predicate device	K993948
Concurrence:	06 Jan 2000
Original Trade Name:	SIS Wound Dressing II
Current Trade Name :	OASIS Wound Matrix Changed 31 May 2002 with FDA acknowledgement
Manufacturer of predicate device:	Cook Biotech Incorporated

Product Information Applicable to all Applications:

Common or Usual or Classification Name: Biologically derived, collagen based wound care product; Liquid bandage.

Trade Name: OASIS Wound Matrix

Model Numbers:

8213-1000-10, 8213-1000-15, 8213-1000-20, 8213-1000-25, 8213-1000-33, 8213-1000-37, 8213-6010-71, 8213-6020-71, 8213-6010-72, 8213-6020-72, 8213-6010-33, 8213-6010-37, 8213-6011-71, 8213-6021-71, 8213-6011-72, 8213-6021-72, 8213-6011-33, 8213-6011-37, 8213-2000-10, 8213-2000-15, 8213-2000-20, 8213-2000-25, 8213-2000-33, 8213-2000-37, 8213-3000-20, 8213-6030-72, 8213-6031-72, 8213-4000-20, SLS-1-3X3.5-FB, SLS-1-3X7-F, SLS-1-3X7-FB, SLS-1-7X10-F, SLS-1-7X10-M, SLS-1-7X10, SLS-1-7X20-F, SLS-1-7X20-M, SLS-1-7X20

COVER SHEET continued

Product Classification Information:

Product Code:	KMF
CFR Section:	880.5090
Device Class:	Class II*

*This is shown above as Class II since a 510(k) has been required based on historical precedent.
CFR 880.5090 lists this device as Class I.

Device Classification Regulation CFR 880.5090

Performance Standards:

No Performance Standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Liquid bandages.

Classification Panel:

General and Plastic Surgery Devices

Indications (From labeling): The Oasis Wound 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.

FDA Document number _____

Manufacturing Site Information

Manufacturer:	Cook Biotech Incorporated
Establishment Registration Number:	1835959
Street Address:	1425 Innovation Place
City:	West Lafayette
State:	Indiana
Country:	USA
ZIP/Postal Code:	47906
Phone Number:	765-497-3355
Fax Number:	765-497-2361
Contact Name:	Perry W. Guinn
Contact Title:	VP QA/RA
Contact Phone Direct Line:	B4 [redacted]
Contact email:	guinn@cookbiotech.com
Alternate Contact Name:	Umesh Patel
Alternate Contact Title:	VP Product Development
Contact Phone Direct Line:	B4 [redacted]
Contact email:	patel@cookbiotech.com

Contract Sterilizer Site Information

Contract Sterilizer:	Cook Incorporated
Establishment Registration Number:	1820334
Street Address:	6300 North Matthews Drive
City:	Ellettsville
State:	Indiana
Country:	USA
ZIP/Postal Code:	47429
Phone Number:	812-339-2235
Fax Number:	812-876-7798
Contact Name:	Art Harris
Contact Title:	Sterilization Manager
Contact email:	aharris@cook-inc.com

Labeling and Intended Use

Draft labels and Instructions for Use can be found in Attachment 1.

Intended use is limited to Indications for Use previously cleared under K993948 for predicate device.

Indications for Use can be found in Attachment 2.

Device Description and Comparison

The OASIS Wound Matrix is:

1. manufactured from porcine Small Intestinal Sub-mucosa (SIS).
2. sizes from 2 cm x 2 cm to 20 cm x 40 cm.
3. acellular
4. lyophillized single layer sheets
5. nominal thickness 40 microns to 500 microns
6. sterile
7. packaged in double peel pouches or single peel pouches
8. one-time use

Detail of Proposed B4 Change:

B4

Proposed Modified B4

B4
B4

Reason for the change:

B4

Effects of the B4 change:

B4

Summary of Design Control Activities

The modifications to the OASIS Wound Matrix device have been assessed through our Design Control Process. This process includes a Risk Assessment (Process FMECA) as well as Design Verification to demonstrate that the modified device meets predetermined Acceptance Criteria. The design verification or validation tests were performed as a result of this risk analysis assessment and predetermined Design Input requirements. The modified OASIS Wound Matrix device was developed under Cook Biotech Internal Design Control procedures as required by 21 CFR 820.30.

Cook Biotech's Design Control Procedures are inclusive of the following elements:

- Design and Development Planning
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Design Transfer
- Design Changes
- Design History File

The biocompatability of the material is well established. The proposed B4 is a return to a previously cleared B4 developed by B4 B4

Devices. Full testing per the ISO 10993-1 requirements was done relative to that submission. That submission included B4

SIS and the resulting Oasis product are complex extracellular matrices with several non-collagenous components. Because we desire to B4 B4 we have a set of internal measurements B4 that were included in our verification studies to compare equivalence between B4 B4

Verification or Validation Tests

The tests listed below are in addition to the full battery of ISO 10993-1 tests done on the [redacted].

Modification: [redacted]

Test Performed	Acceptance Criteria
cytotoxicity	Device is substantially equivalent to the predicate device in ISO 10993 test for cytotoxicity.
acute systemic toxicity	Device is substantially equivalent to the predicate device in test for acute systemic toxicity.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	Device substantially equivalent to predicate device.
[redacted]	Device is substantially equivalent to the predicate device.
[redacted]	[redacted]
[redacted]	[redacted]
Physical properties	Device is substantially equivalent to the previous device.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Conclusion: All results obtained during our design verification tests for this product line and summarized above have met the acceptance criteria. Therefore, we consider this modification to the OASIS Wound Matrix to be acceptable with respect to Design Verification and Validation activities.

Results of testing provide reasonable assurance that the OASIS Wound Matrix, subject of this 510(k), will function as intended and B4 [redacted].

A declaration of conformity with design controls is included in Attachment 3.

Substantial Equivalence

The modified OASIS Wound Matrix has the following similarities to the predicate device which previously received 510(k) concurrence:

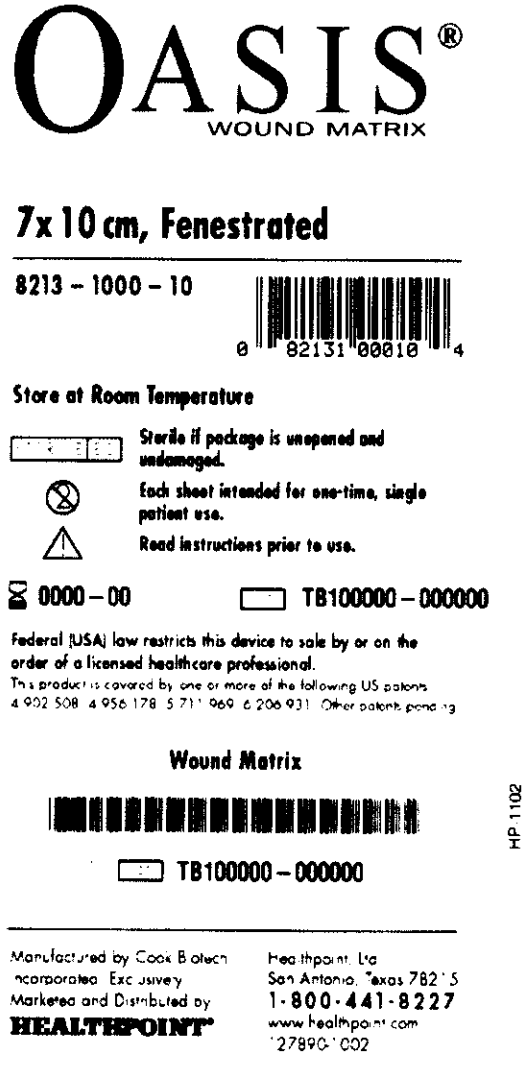
- has the same indicated use,
- uses the same operating principle,
- incorporates the same design,
- incorporates the same basic materials,
- meets the same internal inspection criteria, in-process tests, and final release criteria,
- has the same shelf life, and
- packaged and sterilized using the same materials and processes.

In summary, the OASIS Wound Matrix products described in this submission are, in our opinion, substantially equivalent to the predicate device.

Attachment 1

All labels are unchanged from predicate. Samples of predicate and subject labels are below.

Labels:



83

OASIS®
WOUND MATRIX

7x10 cm, Meshed

8213 – 1000 – 15

0 82131 00015 9

Store at Room Temperature

Sterile if package is unopened and undamaged.

Each sheet intended for one-time, single patient use.

Read instructions prior to use.

0000 – 00 TB100000 – 000000

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

This product is covered by one or more of the following US patents 4,902,508 4,956,178 5,711,969 6,206,931 Other patents pending

Wound Matrix

TB100000 – 000000

HP-1102

Manufactured by Cook Biotech Incorporated Exclusively Marketed and Distributed by
HEALTHPOINT

Healthpoint, Ltd
San Antonio, Texas 78215
1-800-441-8227
www.healthpoint.com
127891.1002

OASIS®
WOUND MATRIX

7x20 cm, Fenestrated

8213 – 1000 – 20

0 82131 00020 3

Store at Room Temperature

Sterile if package is unopened and undamaged.

Each sheet intended for one-time, single patient use.

Read instructions prior to use.

0000 – 00 TB100000 – 000000

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

This product is covered by one or more of the following US patents 4,902,508 4,956,178 5,711,969 6,206,931 Other patents pending

Wound Matrix

TB100000 – 000000

HP-1102

Manufactured by Cook Biotech Incorporated Exclusively Marketed and Distributed by
HEALTHPOINT®

Healthpoint, Ltd
San Antonio, Texas 78215
1-800-441-8227
www.healthpoint.com
127892-1002

HEALTHPOINT®
OASIS®
WOUND MATRIX

FP0003-5A

Distributed by:
Healthpoint, Ltd.
San Antonio, Texas 78215
Toll free: 1-800-441-8227
Tel: 1-817-900-4079 www.healthpoint.com

COOK®
Manufactured by: sis® Technology

Cook Biotech Incorporated

INTENDED USE:

OASIS is indicated for the management of wounds including:
- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Drainage wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)

OASIS 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 OASIS.
- 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.
- OASIS should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled.

POTENTIAL COMPLICATIONS: The following complications are possible. 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.

SUGGESTED INSTRUCTIONS FOR USING OASIS
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 OASIS using aseptic technique.

1. Prepare wound area using standard methods to ensure wound is free of debris and necrotic tissue. An initial surgical debridement of the wound may be necessary to ensure the wound edges contain viable tissue.

2. To apply, cut the dry sheet 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. Overlap adjoining sheets to provide coverage of the entire wound. For ease of handling, apply OASIS 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 OASIS into place to ensure the sheet is in contact with the underlying wound bed.

4. Reapply as needed if OASIS is no longer visible. Typically, reapplication is needed every 3-7 days until the wound is re-epithelialized.

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 OASIS may gradually peel and may be removed during dressing changes. Do not forcibly remove sections of OASIS that may adhere to the wound. Alternatively, OASIS may form a caramel-colored gel, which can be rinsed away with gentle irrigation.

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#136585

Next page is Attachment 2:

Indications for Use Statement are on Attachment 2.

510(k) Number

Device Name **OASIS Wound Matrix**

Indications for Use

The Oasis Wound 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_____ (Per 21 CFR 801. 109)

OR

Over-The-Counter Use_____

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Attachment 3

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Umesh Patel, Ph.D — Date: 16 Jun 06

Vice President, Engineering and Development

Cook Biotech Incorporated

Manufacturing Facility

The manufacturing facility, Cook Biotech Incorporated, 1425 Innovation Place, West Lafayette, IN 47906 is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

Perry Guinn — Date: 16 June 2006

VP Quality Assurance and Regulatory Affairs

Cook Biotech Incorporated

[NOTE: The above two statements should be signed by the designated individual (s) responsible for those activities].

Attachment 4

SPECIAL 510(K) SUMMARY

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
June 15, 2006

Names of Device:

Trade Name:	OASIS® Wound Matrix
Common/Usual Name:	Biologically-derived, collagen-based wound care product
Proposed Classification:	Liquid Bandage 21 CFR 880.5090 (79KMF) Class II, Non-Exempt

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:
The OASIS® Wound Matrix device's intended use is 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 supplied sterile and is intended for one-time use.

Attachment 5

Summary of Substantial Equivalence:

The OASIS® Wound Matrix as described in this submission is substantially equivalent to the predicate SIS Wound Dressing II (Renamed 31 May 2002 OASIS® Wound Matrix) K993948 with respect to the following characteristics:

Similarities:

1. Both have the same intended use.
2. Both use the same operating principle.
3. Both incorporate the same basic design.
4. Both incorporate the same materials.
5. Both have the same shelf-life.
6. Both pass the same set of internal tests and release criteria.
7. Both are packaged and sterilized using the same materials and processes.

Differences:

1. B4 [redacted] that did not affect specifications or performance of the final device.

Statement of Safety and Effectiveness:

The OASIS® Wound Care Matrix meets the functional claims and intended use as described in the product labeling, and is as safe and effective in terms of substantial equivalence as the predicate OASIS Wound Care Matrix described in this document.

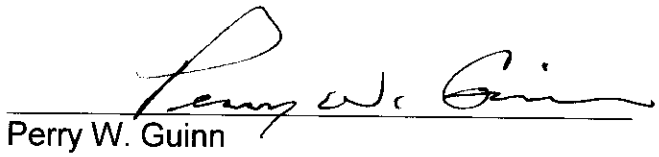
Perry W. Guinn
Vice President, Quality Assurance and Regulatory Affairs
Cook Biotech Incorporated

16 June 2003
Date

Attachment 6

Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(j), I, Perry W. Guinn, certify that, to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Vice President of Quality Assurance and Regulatory Affairs of Cook Biotech Incorporated, and in reliance thereupon, the data and information submitted in this Premarket Notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.



Perry W. Guinn

16 June 2006

Date

Attachment 7

[From FDA Flowchart depicting need to file 510(k) for a modified product.]

Main Flowchart

Materials Change (YES) .... Go to Chart C....

Chart C

Change in material formulation? (YES) ....

Is the device an implant? (NO) ....

Contact Body tissues? (YES)...

Additional 10993 testing needed? (YES)...

Therefore....New 510(k) needed

Attachment 8
Statements

I, Perry W. Guinn, certify that, to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Vice President of Quality Assurance and Regulatory Affairs of Cook Biotech Incorporated, that the intended use / indications for use of the modified device are unchanged and that the modification has not altered the fundamental technology of predicate.

Perry W. Guinn

16 June 2006

Date

Attachment 9

Special 510(k) Screening Checklist

Required Elements for all types of 510(k) submissions:	Page
Cover Letter with elements listed on 3-2 of 510(k) Manual	1
Table of Contents	3
Truthful and Accurate Statement	A6
Device Trade Name, Classification Name, Est. Reg #	4-2, 4-3, 5
Device Classification Regulation. Number. and Class	4-3
Proposed Labeling Including material listed on 3-4 of the 510(k) Manual	A1
Statement of Indications For Use on separate page	A2
Substantial Equivalence Comparison comparing items from 3-4 of 510(k) Manual	11
Description of Device	6
Identification of Predicate device	4-2
Compliance with Performance Standards (Statement)	4-3
Class III Certification and Summary	NA
Financial Certification or Disclosure Statement	NA
510(k) Kit Certification	NA

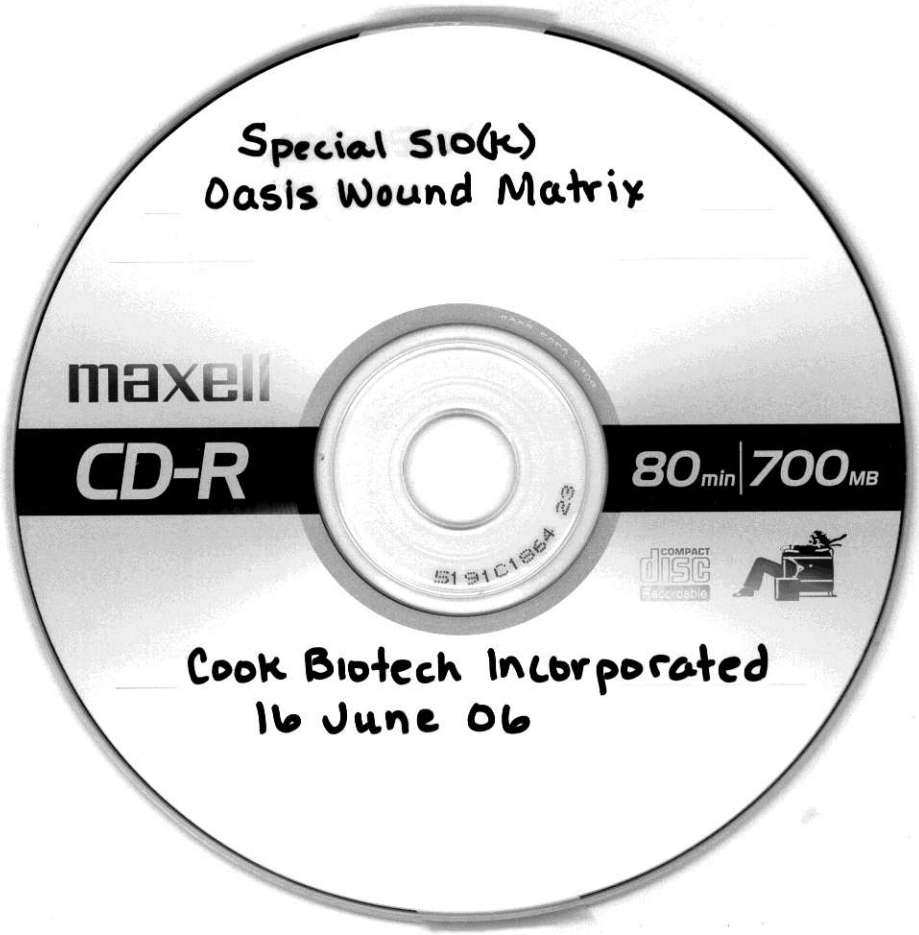
Required Elements for SPECIAL 510(k) Submissions

Name and 510(k) Number of sponsor's own, unmodified predicate device	4-2
Description of modified device and comparison to sponsor's predicate device	6
Statement that intended use / indications of the modified device are unchanged	A8
Statement that modification has not altered fundamental technology of predicate	A8
Summary of Design Control Activities	8
Identification of Risk Analysis method used and results of analysis	8
Verification and Validation Activities, tests and Acceptance criteria	9
Declaration of Conformity with Design Controls	A3

Declaration to Include:

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 acceptance criteria were met. Signed by 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. Signed by individual responsible for those particular activities.


Special 510(k)
Oasis Wound Matrix
maxell
CD-R
80min | 700MB
COMPACT
disc
Recordable
Cook Biotech Incorporated
16 June 06

(1)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

July 7, 2006

From: Reviewer(s) - Name(s) [signature] DXK

Subject: 510(k) Number K061711

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

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

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

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☑ YES ☐ NO 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 day

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

79 Hydrophilic Wound/Burn Dressing

unclassified

Review: [signature] PLSB 7/18/06
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 7/18/06
(Division Director) (Date)

4

Revised:4/2/03

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?	N	A
3. Have you verified that the Document is labeled Class III for GMP purposes?	N	A
4. If, not, has POS been notified?	N	A
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)?	N	A
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.	N	A

7

(8)

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

K 061711

Reviewer: [signature]

Division/Branch: DGRND / PRSB

Device Name: Oasis Wound Matrix

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

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		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?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		✓	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?		✓	If YES = Stop NE
9. Accepted Scientific Methods Exist?	✓		If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		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.

8

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.

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 [redacted] effectiveness: B4

7. Explain how des[redacted]

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

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE RE: DOCUMENT NUMBER K061711 J. Rhodes 7/18

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: K993948, SIS Wound Dressing II.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials. Attachment 8.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed** – page 7.

This change was for B4 [redacted]

[redacted]

The new B4 [redacted] is:

[redacted]

B4 [redacted]

Comparison Information (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics. The new B4 [redacted] return B4 [redacted] B4 [redacted] K974540 identified the SIS Hernia Repair product which was cleared including the [redacted] B4 [redacted]

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B4 [redacted]

Since the B4 [redacted], I asked the sponsor to provide the following:

- "specifications for the following tests: B4 [redacted]. In addition, please provide the risk assessment and research opinion that concludes there is no risk to the B [redacted] with respect to the B4 [redacted] change."

With respect to a possible effect on B4 [redacted] B4 clarified that the [redacted] I agree. For the specifications regarding B4 [redacted] The values of the new product lots are not different from the old product lots produced using the original B4 [redacted] Also, 36 lots of product were found to contain the same extent of differentiative character as 4 product lots manufactured under the original manufacturing process. Physical characteristics evaluated included B4 [redacted] No data for these evaluations was provided however, the sponsor states that product manufactured will meet the original specifications.

4. A **Design Control Activities Summary** which includes:
   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 verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

   Both statements provided in attachment 3.

5. A **Truthful and Accurate Statement (attachment 6)**, a **510(k) Summary (attachment 4)** and the **Indications for Use Enclosure (attachment 2).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices

demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

(Reviewer's Signature)

7/7/06
(Date)

Comments:
Indications for Use statement on the new IFU form requested.
Specifications of B4 [redacted] s and risk assessment regarding B4 [redacted] requested.

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Attachment 4 (Modified 18 July 2006)

SPECIAL 510(K) SUMMARY

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
July 18, 2006

Names of Device:

Trade Name:	OASIS® Wound Matrix
Common/Usual Name:	Animal-derived, extracellular matrix wound care product
Classification:	Liquid Bandage (KMF) Unclassified

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:

The OASIS® Wound Matrix device's intended use is 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 supplied sterile and is intended for one-time use.

K061711

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Attachment 4 (Modified 10 July 2006)

SPECIAL 510(K) SUMMARY

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
July 10, 2006

Names of Device:

Trade Name:	OASIS® Wound Matrix
Common/Usual Name:	Biologically-derived, collagen-based wound care product
Proposed Classification:	Collagen-based Wound Dressing (79KGN) Unclassified

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:

The OASIS® Wound Matrix device's intended use is 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 supplied sterile and is intended for one-time use.

Date: 10 July 2006
To: Peter Hudson, FDA
From: Perry Guinn, Cook Biotech Inc.
Subject: K061711 Questions on [redacted]

Peter,

There are good reasons for [redacted] These are, of course, the negative controls [redacted]

The physical presence of the [redacted] This could account for some variability in the negative controls.

The best explanation for the validity of the assay is as follows:

1. The negative controls (aka blanks) in this assay were [redacted]
2. [redacted] was performed comparing the sample data for each plate versus the negative controls for that plate. The results of the t-test are as follows:
   a. Plate 1 (# negative controls = 3, # samples = 72): p = 0.31
   b. Plate 2 (# negative controls = 3, # samples = 36): p = 0.32

   These results show that there is no statistically significant difference between the negative controls and the samples, arguing for the [redacted] in the samples.

The acceptance criteria for the [redacted] test is for the [redacted]

Another way of looking at the data:

[redacted]

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When we consider that the acceptance criteria only requires the means of the Sample and the Positive control to be below and above the [redacted] e fact that the mean of the Positive Control is [redacted] is highly significant.

I hope this helps to clarify the confusion. If you need further information, please let me know.

Kind regards,

Perry

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Indications for Use

510(k) Number (if known): K061711

Device Name: Oasis Wound Matrix

Indications For Use:
The Oasis Wound 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Hudson, Peter

From: Perry Guinn [pguinn@CookBiotech.com]
Sent: Friday, July 07, 2006 2:57 PM
To: Hudson, Peter
Cc: B4 [redacted]
Subject: K 061711 telecon follow up

Dear Peter,

Pasted below is a memo from B4 [redacted] that addresses the two concerns raised in the telephone conference today:

1. The issue B4 [redacted].

2. The B [redacted] for comparing B4 [redacted] B4 [redacted] new in the B4 [redacted] showing no significant difference.

With regard to a statement regarding claims we declare:

"We are not making any new claims for this device based on this submission. All testing was done for the purpose of establishing B4 [redacted] to the predicate product."

I hope this answers all of your questions. Please call if you need something else.

Kind regards,
Perry

Here is the B4 [redacted] memo to me:
Perry,
These comments are in response to the questions raised in the conference call with Dr. Peter Hudson from the FDA (~1:30 p.m., 07Jun06).

Question on B4 [redacted].
The positive controls B4 [redacted]
B4 [redacted]

Question on B4 [redacted].
A statistical comparison was made between the historical data B4 [redacted]
B4 [redacted]

Regards,

B4 [redacted]

Research Engineer
Cook Biotech, Inc.

Hudson, Peter

From: Perry Guinn [pguinn@CookBiotech.com]
Sent: Friday, July 07, 2006 4:02 PM
To: Hudson, Peter
Cc: B4 [redacted]
Subject: RE: K 061711 telecon follow up

Peter,

Sorry for any confusion. Your latter assessment and my memo paint the accurate picture. Of course, the bottom line from a safety perspective is that the [redacted]

B [redacted] Thus we can safely say that the tissue B4 [redacted]

Perry

From: Hudson, Peter [mailto:peter.hudson@fda.hhs.gov]
Sent: Friday, July 07, 2006 3:16 PM
To: Perry Guinn
Cc: B4 [redacted]
Subject: RE: K 061711 telecon follow up

Hi Perry,

Sorry but I guess I misunderstood some of the information. When B4 [redacted] and B4 [redacted] were commenting on the [redacted] I thought they B4 [redacted] Subsequently in the conversation B4 [redacted] B4 [redacted] Just confirm this either way. If the latter is correct then the argument would be that the B4 [redacted]

Peter

From: Perry Guinn [mailto:pguinn@CookBiotech.com]
Sent: Friday, July 07, 2006 2:57 PM
To: Hudson, Peter
Cc: B4 [redacted]
Subject: K 061711 telecon follow up

Dear Peter,

Pasted below is a memo from B4 [redacted] addresses the two concerns raised in the telephone conference today:

B4 [redacted]

2. The B4 values B4 showing no significant difference.

With regard to a statement regarding claims we declare:

"We are not making any new claims for this device based on this submission. All testing was done for the purpose of establishing B equivalence to the predicate product."

I hope this answers all of your questions. Please call if you need something else.

Kind regards,
Perry

Here is the B4 memo to me:
Perry,
These comments are in response to the questions raised in the conference call with Dr. Peter Hudson from the FDA (~1:30 p.m., 07Jun06).

B4
The positive controls were B4
B4 positive controls were tested at the same time B4

Question on B4 assessment.
A statistical comparison was made between the historical data on the previous B4 OASIS devices and the new B4 OASIS devices. The data is contained on page 10.0 of the K 061711 addendum 07 July 2006. The previous B4 OASIS had B4

Regards,
B4
Research Engineer
Cook Biotech, Inc.

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Cook Biotech Inc.

Memo

To: B4 [redacted]

From: [redacted]

CC: [redacted]

Date: [redacted]

Re: [redacted]

B4 [redacted]

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B4 Design Specifications

B4 Design Specifications

B4 Design Specifications

CTS

Center Tracking System

FDA

Summary

Document #: DR980257 Workflow: Approved

Product Code: KMF Device Status:

Review Panel: Lead Center:

Definition:

Reason: Associated Doc Num: *None*

Device/Product Name:

Synonym(s): Dressing

Additional Details

Regulation:

Use: Therapeutic Regulation Med Specialty: HO

Radiation Emitting:

Class: Date Reclassified:

Submission Type:

Attributes

Implant > 30 days:	Releasable:
Predicate:	May Proceed %:
Tracked Device:	De Novo:
Life Sustaining:	Significant Risk:
MRA Third Party:	Third Party:
GMP Exempt:	

Medical Specifications

Intended Use:

Indication for Use:

Technical Method:

Physical State:

Target Area:

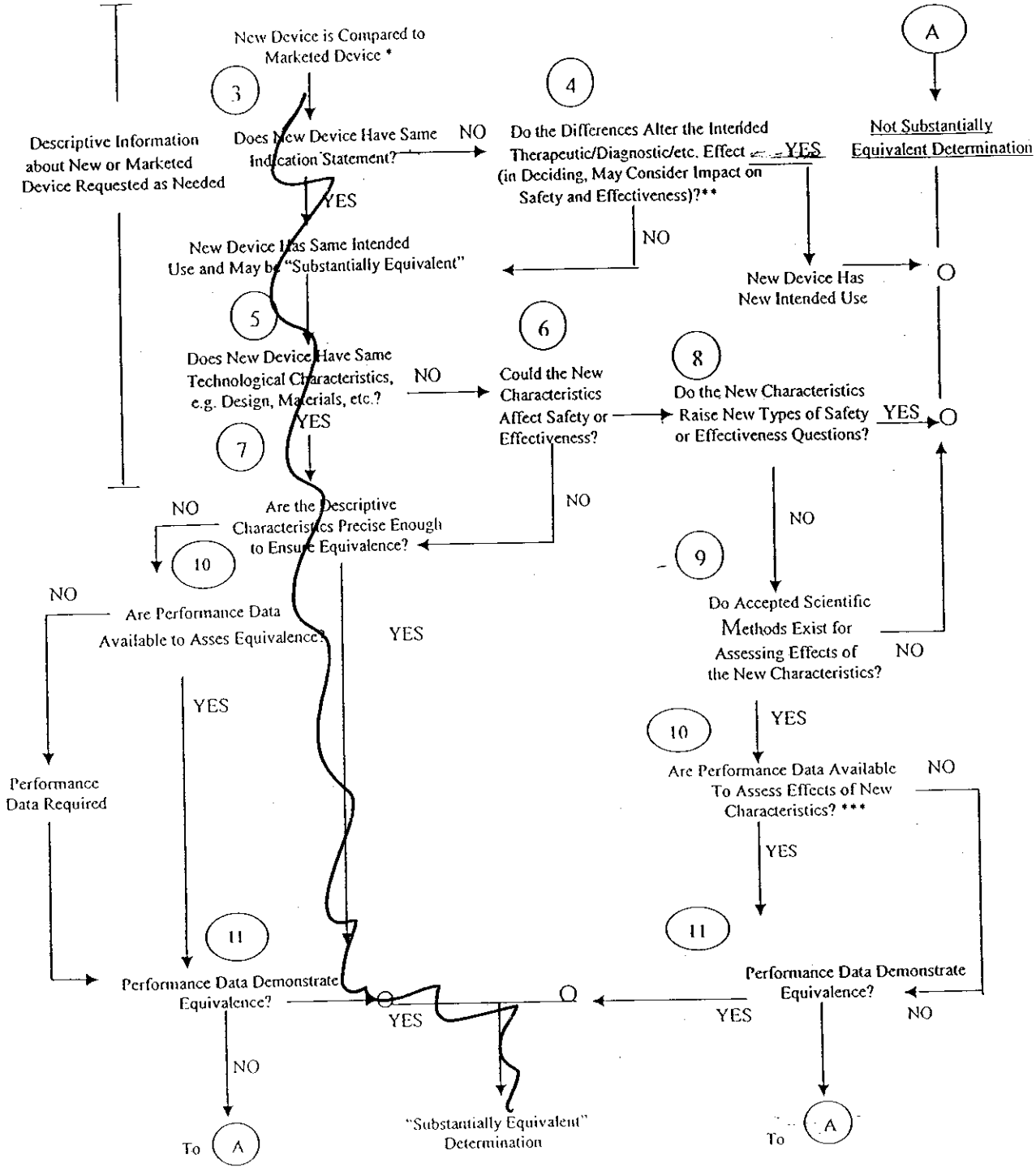
KMF is class I.
The correct product code is KGN

Decisions

Division: Approved
Evaluator: Approved

Associated Information

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



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

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

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