

JAN - 6 2000

K993948

9. 510(K) SUMMARY

Submitted By:

Neal E. Fearnot, Ph.D.
President
Cook Biotech, Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355

November 18, 1999

Device:

Trade Name:	SIS Wound Dressing II
Common/Usual Name:	Topical Wound Dressing
Proposed Classification Name:	Unclassified (79KMF)

Intended Use:

The SIS Wound Dressing II 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 SIS Wound Dressing II is similar to predicate collagen-based wound dressings that are currently marketed for the management of wounds including the SIS Wound Dressing (D.C. #K973170) manufactured by Cook Biotech, Incorporated, the FIBRACOL * Plus Collagen Wound Dressing with Alginate (D.C. #K982597) manufactured by Johnson and Johnson Medical, and the SkinTemp® Kollagen Wound Management Material (D.C. #K913023) and Medifil® Kollagen Particles (D.C. #K910944) manufactured by Biocore Medical Technologies.

Device Description:

The SIS Wound Dressing II 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 SIS Wound Dressing II is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.

Discussion of Tests and Test Results:

The SIS Wound Dressing II was subjected to a panel of tests to assess biocompatibility. The SIS Wound Dressing II 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

MAR 19 2007

Neal E. Fearnot, Ph.D.
President
Cook Biotech, Inc.
3055 Kent Avenue
West Lafayette, Indiana 47906

Re: K993948
Trade Name: SIS Wound Dressing II
Regulatory Class: Unclassified
Product Code: KGN
Dated: November 18, 1999
Received: November 22, 1999

Dear Dr. Fearnot:

This letter corrects our substantially equivalent letter of January 6, 2000.

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 (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.

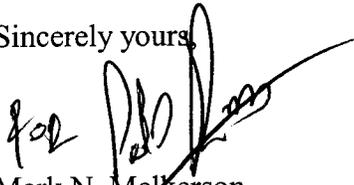
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Sincerely yours,



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

510(k) Number (if known): K 993948

Device Name: SIS Wound Dressing II

Indications For Use:

The SIS Wound Dressing II 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)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K993948

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____