

APR 30 1998

10

510(k) Premarket Notification
SIS Wound Dressing

K973170

I. 510(K) SUMMARY

Submitted By:

Neal E. Fearnot, Ph.D., E.E.
President
Cook Biotech, Incorporated
P.O. Box 2402
West Lafayette, IN 47906
(765) 497-3355
August 22, 1997

Device:

Trade Name: SIS Wound Dressing

Common/Usual Name: Wound Dressing, Burn Dressing, Porcine Burn Dressing

Proposed Classification Name: Not Classified,
FDA proposed classification:
Porcine Burn Dressings
21 CFR Part 878.4026 or 878.4140, (79^{KMF}~~KGN~~)

Predicate Devices:

The SIS Wound Dressing is similar to predicate tissue-derived wound dressings that are currently marketed, having the same intended use of temporary coverage of partial-thickness skin loss injuries.

Device Description:

The SIS Wound Dressing is supplied in sheet form in sizes ranging from 16 cm² to 360 cm². The device is supplied sterile and is intended for one-time use. Reasonable assurance of biocompatibility of the materials comprising the SIS Wound Dressing is provided by the established history of use of porcine-derived tissues in medical product manufacturing as well as meeting the requirements of the appropriate biocompatibility tests.

Substantial Equivalence:

The SIS Wound Dressing will be manufactured according to specified process controls and a Quality Assurance Program. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

Neal E. Fearnot, Ph.D.
President
Cook Biotech Incorporated
Box 2603, 3055 Kent Avenue
West Lafayette, Indiana 47906

Re: K973170
Trade Name: SIS Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 27, 1998
Received: March 30, 1998

Dear Dr. Fearnot:

This letter corrects our substantially equivalent letter of April 30, 1998.

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 and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

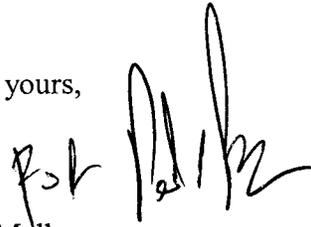
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', written over a faint, larger version of the same signature.

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

K973170

510(k) Number (if known): K973170

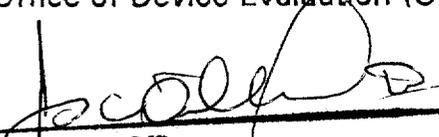
Device Name: SIS Wound Dressing

Indications For Use:

The SIS Wound Dressing is intended for temporary coverage of partial-thickness skin loss injury, such as burns, abrasions, decubitus and chronic vascular ulcers, and autograft donor sites. This 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 **K973170**
510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)