K090812
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510(K) Summary

JUL 30 2009

Submitter
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Device Information

Trade Name: TheraForm™ Standard / Sheet

Common Name: Wound Dressing

Classification Name: Dressing, Wound, Collagen

Product Code: KGN

Regulation Number: N / A

Device Class: Class II

General Description

TheraForm™ Standard / Sheet Absorbable Collagen Membrane is a sterile, pliable porous wound dressing made of highly purified collagen derived from porcine. TheraForm™ Standard / Sheet is completely absorbable and highly biocompatible.

Indication for Use

TheraForm™ Standard / Sheet is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic 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

The subject device is substantially equivalent to the following predicate devices:

- PriMatrix Dermal Repair Scaffold (K061407) manufactured by TEI BIO Sciences Inc.

Comparison to Predicate Devices

Comparisons have established that the subject of TheraForm™ Standard / Sheet is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

Performance Data

TheraForm™ Standard / Sheet was subjected to a panel of tests to assess biocompatibility and it passed the requirements of all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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% Kodent, Inc.
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Santa Fe Springs, California 90670

JUL 30 2009

Re: K090812
Trade/Device Name: TheraForm™ Standard/Sheet
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 15, 2009
Received: July 15, 2009

Dear Jung Bae Bang:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number: K090812

Device Name: TheraForm™ Standard / Sheet

Indication for Use:

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- Draining wounds

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 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)

David Krone for M&M

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090812