SEP 2 9 2003

510(k) Summary

This 510(k) summary for DressSkin is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by

TEI Biosciences Inc.
7 Elkins Street
Boston, MA 02127
(617) 268-1616
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Contact Person

Kenneth James, Ph.D.
Director of Product Development and Applied Research

Date Prepared

November 8, 2002

Device Information

Proprietary name: DressSkin
Classification name: Wound dressing
Device classification: Class II

Device Description

DressSkin is a collagen wound dressing. The device is supplied sterile and is provided in sheet form in a variety sizes to be trimmed by the surgeon to meet the individual patient's needs.

Intended Use

DressSkin is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds—abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Legally Marketed Devices to which Equivalence is Being Claimed

DressSkin™ is substantially equivalent in function and intended use to:

Predicate Devices	Manufacturer	510(k) Number
SIS Wound Dressing II	Cook Biotech	K993948
Fibracol Plus Collagen Wound Dressing	Johnson & Johnson Medical	K982597

Summary of Technological Characteristics and Biocompatibility

DressSkin™ is substantially equivalent to other wound dressings with respect to its design as a flexible, collagen sheet which can be used to cover wounds.

A rigorous biocompatibility assessment performed by an independent certified laboratory demonstrated the biocompatibility of DressSkin™. The tests performed included: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, genotoxicity, hemolysis, and pyrogenicity. The manufacturing methods for DressSkin™ were also tested by an independent laboratory to assure safe levels of viral inactivation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2003

Kenneth James, Ph.D.
Director of Product Development
and Applied Research
TEI Biosciences, Inc.
7 Elkins Street
Boston, Massachusetts 02127

Re: K023778
Trade/Device Name: DressSkin™
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 2, 2003
Received: July 3, 2003

Dear Dr. James:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

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

2. Indications for Use of the Device

510(k) Number (if known):

Device Name: DressSkin™

Indications for Use:

DressSkin is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds—abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023778