K011026

JUN 13 2001

510(K) SUMMARY

Submitted by:
Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

Contact
Patrick R. Bilbo
Telephone: (781) 401-1155
Facsimile: (781) 401-1109

Date: April 4, 2001

Device:

Trade Name:	FortaDerm™ Wound Dressing
Common/Usual Name:	Topical Wound Dressing, Wound Management Biomaterial
Classification Name:	Dressing, Wound (79KMF)
Classification:	Unclassified

Predicate Device:
The relevant predicate device is the SIS Wound Dressing II (K993948) manufactured by Cook Biotech, Incorporated.

Statement of Substantial Equivalence:
The FortaDerm Wound Dressing is similar with respect to intended use, technological characteristics, materials and physical construction to the predicate device in terms of section 510(k) equivalency.

Intended Use:
The FortaDerm Wound Dressing 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, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is intended for one-time use.

Device Description:
FortaDerm Wound Dressing consists of a single-layer fenestrated sheet of porcine intestinal collagen. FortaDerm Wound Dressing is supplied dry in sheet form in sizes ranging from 5 x 5 cm to 12 x 36 cm. The device is packaged in sterile, sealed single pouches.

Performance Data:
FortaDerm Wound Dressing was subjected to a number of tests to assess biocompatibility and performance. The device 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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Mr. Patrick Bilbo
Director, New Products
Organogenesis, Inc.
150 Dan Road
Canton, Massachusetts 02021

Re: K011026
Trade Name: FortaDerm™ Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 4, 2001
Received: April 4, 2001

Dear Mr. Bilbo:

This letter corrects our substantially equivalent letter of June 13, 2001.

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.

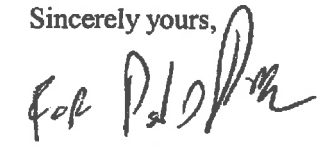
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

INDICATIONS FOR USE STATEMENT

Applicant: Organogenesis, Inc.

510(k) Number (if known): K011026

Device Name: FortaDerm™ Wound Dressing

Indications For Use:

The FortaDerm™ Wound Dressing 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, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and 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)

for Mark N Melkerson

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

510(k) Number K011026

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)