K070557

VIII. 510(k) Summary

MAY 23 2007

A. Sponsor/Submitter:

Marine Polymer Technologies, Inc.
107 Water Street
Danvers, MA 01923
Phone: 781-270-3200
Fax: 781-270-1133

B. Contact Person

Sergio Finkielsztein
President
Phone: 781-270-3200 x 13

C. Date of Submission:

February 15, 2007

D. Trade (Brand) Name:

TALIDERM™

E. Common Name:

Dressing, Wound Hydrophilic

F. Classification Number/ Name:

Unclassified

G. Regulatory Class:

H. Product Code:

FRO

I. Predicate Devices:

Marine Polymer Technologies, Inc.- SyvekPatch (K984177) and SyvekNT(K022673)
Marine Polymer Technologies, Inc. - RDH Bandage (K002550)
Tissue Technologies Holdings LLC – TT101 Wound Care Dressing (K061060)
TEI Biosciences Inc. Dress Skin (K023778)
J&J Medical Ltd.- PROMOGRAN Matrix Wound Dressing (K014129)

J. Intended Use:

TALIDERM™ is intended for use under the direction of a healthcare professional.

TALIDERM™ is indicated for the management of wounds including:
Diabetic ulcers
Venous ulcers
Pressure wounds
Ulcers caused by mixed vascular etiologies
Full thickness and partial thickness wounds
Second degree burns
Surgical wounds-donor sites/grafts, post-mohr's surgery, and other bleeding surface wounds
Abrasions
Traumatic wounds healing by secondary intention
Dehisced surgical wounds.

K. Device Description:

TALIDERM™ is a sterile primary wound dressing comprised of shortened fibers of poly-N-acetyl glucosamine, isolated from microalgae.

L. Summary of Substantial Equivalence:

Marine Polymer Technologies has submitted information on indication for use, biocompatibility and performance characteristics to establish that TALIDERM™ is substantially equivalent to currently marketed predicate devices. TALIDERM™ has essentially the same intended use as the predicate devices. Results of scientific testing have ensured that the material is biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. Non-clinical testing was conducted. Animal testing was performed to simulate clinical conditions with no adverse effects noted. Clinical evidence further supported the safety and performance of TALIDERM™ .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Marine Polymer Technologies
% Mr. Sergio Finkielsztein
President
107 Water Street
Danvers, Massachusetts 01923

MAY 23 2007

Re: K070557
Trade/Device Name: Taliderm™
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 12, 2007
Received: April 13, 2007

Dear Mr. Finkielsztein:

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 (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/industry/support/index.html.

Sincerely yours,

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

Enclosure

Appendix 2:

Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known) K 070557

Device Name TALIDERM™

TALIDERM™ is indicated for the management of wounds including:
Diabetic ulcers
Venous ulcers
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Surgical wounds-donor sites/grafts, post-mohr's surgery, and other bleeding surface wounds
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Dehisced surgical wounds.

TALIDERM™ is intended for use under the direction of a healthcare professional.

Prescription Use ___X_ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070557