Attachment 1

K072760

JUN 17 2008

510(k) Summary Statement for Envela™ (Hydrohesive™ Occlusive Dressing)

Device Classification Name:	Occlusive dressing
Common/Usual Name:	Occlusive dressing
Proprietary Name:	Envela™ (Hydrohesive™ Occlusive Dressing)
Classification:	Class I General Controls (21 CFR 878.4020, 4022)
Performance Standards:	Not Applicable
Predicate Devices:	DuoDerm® Extra Thin (Extra Thin® CGF Dressing) for its moisturizing and occlusive properties; Compeed Psoriasis Dressing and Hydrocolloid Dressing for Psoriasis for management of psoriasis and protection of psoriatic plaques.
Sponsor/Establishment:	Teikoku Pharma USA, Inc 1718 Ringwood Avenue San Jose, CA 95131-1711
Establishment Registration Number:	To be assigned.
Contact Person:	Andrew Korey, PhD Chief Scientific Officer
Summary Date:	June 6, 2008
Statement of Intended Use:	- For use in the management of psoriasis and the protection of psoriatic plaques - As a protective dressing - For management of superficial, dry to lightly exudating dermal wounds."
Comparison to Predicate Device:	Envela™ is substantially similar in terms of component materials, shape, dimensions, and mode of action to existing occlusive wound dressings.
Performance Standards:	Not applicable to Class I occlusive dressings; subject to General Controls.
Proposed Labeling:	The text for the individual foil envelope, carton label, Package Insert (including Instructions for Use) will be updated if and when the Indications for Use have been cleared by FDA. Promotional literature and advertising for the device have not yet been prepared.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2008

Teikoku Pharma USA, Inc.
% Margie Nemcik-Cruz, MA, RAC
Regulatory Affairs Consultant
1718 Ringwood Avenue
San Jose, California 95131-1711

Re: K072560
Trade/Device Name: Envela™ (Hydrohesive™ Occlusive Dressing)
Regulation Number: 21 CFR 878.4020
Regulation Name: Occlusive wound dressing
Regulatory Class: I
Product Code: NAD
Dated: June 6, 2008
Received: June 9, 2008

Dear Ms. Nemcik-Cruz:

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.

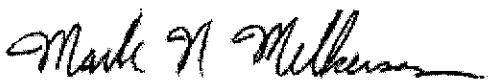
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Attachment 1

K072560

Indications for Use Statement
(Food Drug and Cosmetic Act, Section 502(f)(1))

510(k) Number (if known):	To be assigned
Device Name:	Envela™ (Hydrohesive™ Occlusive Dressing)
Indications for Use:	-For use in the management of psoriasis and the protection of psoriatic plaques -As a protective dressing - For management of superficial, dry to lightly exudating dermal wounds."

Prescription Use _____ OR Over-the-Counter Use ___√___

(21 CFR 801 SUBPART D) **(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)

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

510(k) Number K072560

007