DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Choice Therapeutics
% Hogan & Hartson LLP
Mr. Howard M. Holstein
Columbia Square
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K073213
Trade/Device Name: TheraBond Antimicrobial Barrier Systems
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 6, 2008
Received: May 6, 2008

Dear Mr. Hostein:

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

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

Enclosure

K073213
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Section 5 – 510(k) Summary

MAY 28 2008

Owner's Name:	Choice Therapeutics
Address:	One Apple Hill Road, Suite 316 Natick, MA 01760
Telephone Number:	(508) 720-9803
Fax Number:	(508) 650-0260
Contact Person:	Peter Hamilton, Vice President of Operations
Subject Device Name:	TheraBond Antimicrobial Barrier Systems
Trade Name:	TheraBond
Common/Usual Name:	Wound Dressing (Antimicrobial)
Product Code:	FRO – Dressing, Wound, Drug
FDA Regulation:	N/A
Device Classification:	Unclassified
Predicate Devices:	K981299: Silverlon Contact Wound Dressing (Argentum International, LLC) K023612: Antimicrobial Barrier Wound Contact Dressing, Burn Wrap, Burn Contact Dressing & Silverlon Acute Burn Glove (Argentum International, LLC)
Trade Name:	Silverlon
Common/Usual Name:	Wound Dressing (Antimicrobial)
Product Code:	FRO – Dressing, Wound, Drug
FDA Regulation:	N/A
Device Classification:	Unclassified

Device Description
The TheraBond Antimicrobial Barrier Systems consist of a knitted, flexible, silver-plated nylon-based fabric. The device is available in several sizes and configurations including wound contact dressings, island dressings and wraps.

Intended Use
TheraBond Antimicrobial Barrier Systems are indicated for use in light to moderately exuding partial and full thickness wounds including traumatic wounds, surgical wounds, donor sites, 1st and 2nd degree burns, as well as decubitus ulcers, diabetic ulcers and vascular ulcers. TheraBond may be used over debrided and partial thickness wounds.

Performance Testing
Performance data provided in support of this submission include the results of antimicrobial effectiveness testing, silver ion release testing, silver plating integrity testing and biocompatibility testing in accordance with *ISO 10993: Biological Evaluation of Medical Devices.*

Conclusion
TheraBond Antimicrobial Barrier Systems meet all pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness for its intended use; the TheraBond Antimicrobial Barrier Systems are substantially equivalent to the predicate devices.

Section 4 – Indications for Use Statement

510(k) Number (if known): K073213

Device Name: TheraBond Antimicrobial Barrier Systems

Indications for Use:

TheraBond Antimicrobial Barrier Systems are indicated for use in light to moderately exuding partial and full thickness wounds including traumatic wounds, surgical wounds, donor sites, 1st and 2nd degree burns, as well as decubitus ulcers, diabetic ulcers and vascular ulcers. TheraBond may be used over debrided and partial thickness wounds.

Prescription Use X OR Over-the-Counter Use ____
(Per 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)

Neil R P Ogden for mkm

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

510(k) Number K073213