K090489
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KCI

510(k) SUMMARY
ABThera™ Open Abdomen Dressing

MAY 14 2009

Date prepared	24 February, 2009
510(k) owner	KCI USA, Inc. 6203 Farinon Dr. San Antonio, TX 78249
Name of contact person	Christy Hubbard Oviatt
Trade or proprietary name of the device	ABThera™ Open Abdomen Dressing
Common or usual name	Open Abdomen Wound Dressing
Classification	Class II, CFR 878.3300 Surgical Mesh
Legally marketed device(s) to which equivalence is claimed	V.A.C.® Abdominal Dressing cleared under 510(k) K022011
Device description	The ABThera™ Open Abdomen Dressing is a specialty dressing, supplied sterile for single use only. It is double pouched and packaged as a kit with • One Internal Contact Layer • Two Outer Layer open-cell foam pieces • Four V.A.C.® Drapes • One T.R.A.C.™ Pad Assembly
Material used	The ABThera™ Open Abdomen Dressing is comprised of a polyurethane contact layer, polyurethane open cell foam, and polyurethane film with acrylic adhesive drape.

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Intended use of the device	The ABThera™ Open Abdomen Dressing is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and or repeat abdominal entries are necessary. The Intended use of this system is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome. The intended care setting is the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating theater.	
Differences in intended use from the predicate(s)	The intended use of the device is the same as the predicate.	
Summary of the technological characteristics of the device compared to the predicate device	**Predicate**	**Device**
	• Internal Contact Layer has an oval piece of black foam encased in the center of polyurethane film. • Two black Outer Layer Foam pieces • Four V.A.C.® Drapes • T.R.A.C.™ Pad and Tubing	• Internal Contact Layer has six blue foam extensions radiating out from a central point and encased in polyurethane film. • Two blue Outer Layer Foam pieces • Four V.A.C.® Drapes • T.R.A.C.™ Pad and Tubing
Summary of non-clinical tests	The dressing design was evaluated under a number of design verification and validation tests in order to assure performance and conformance to design specifications.	
Conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device	Verification and validation testing conducted under design control requirements document that the ABThera™ Open Abdomen Dressing is equivalent to the predicate in terms of technology and performance requirements for its intended use.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

KCI USA, Inc.
% Ms. Christy Oviatt
Senior Regulatory Affairs Specialist
6203 Farinon Drive
San Antonio, Texas 78249

Re: K090489
Trade/Device Name: ABThera Open Abdomen Dressing
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 14, 2009
Received: April 15, 2009

Dear Ms. Oviatt:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090489

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **ABThera Open Abdomen Dressing**

Indications for Use:

The ABThera Open Abdomen Dressing is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and or repeat abdominal entries are necessary. The Intended Use of this system is for use in open abdominal wounds, with exposed viscera, including but not limited to, abdominal compartment syndrome.

The intended care setting is the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating theater.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

Daniel Krone for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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