solventum

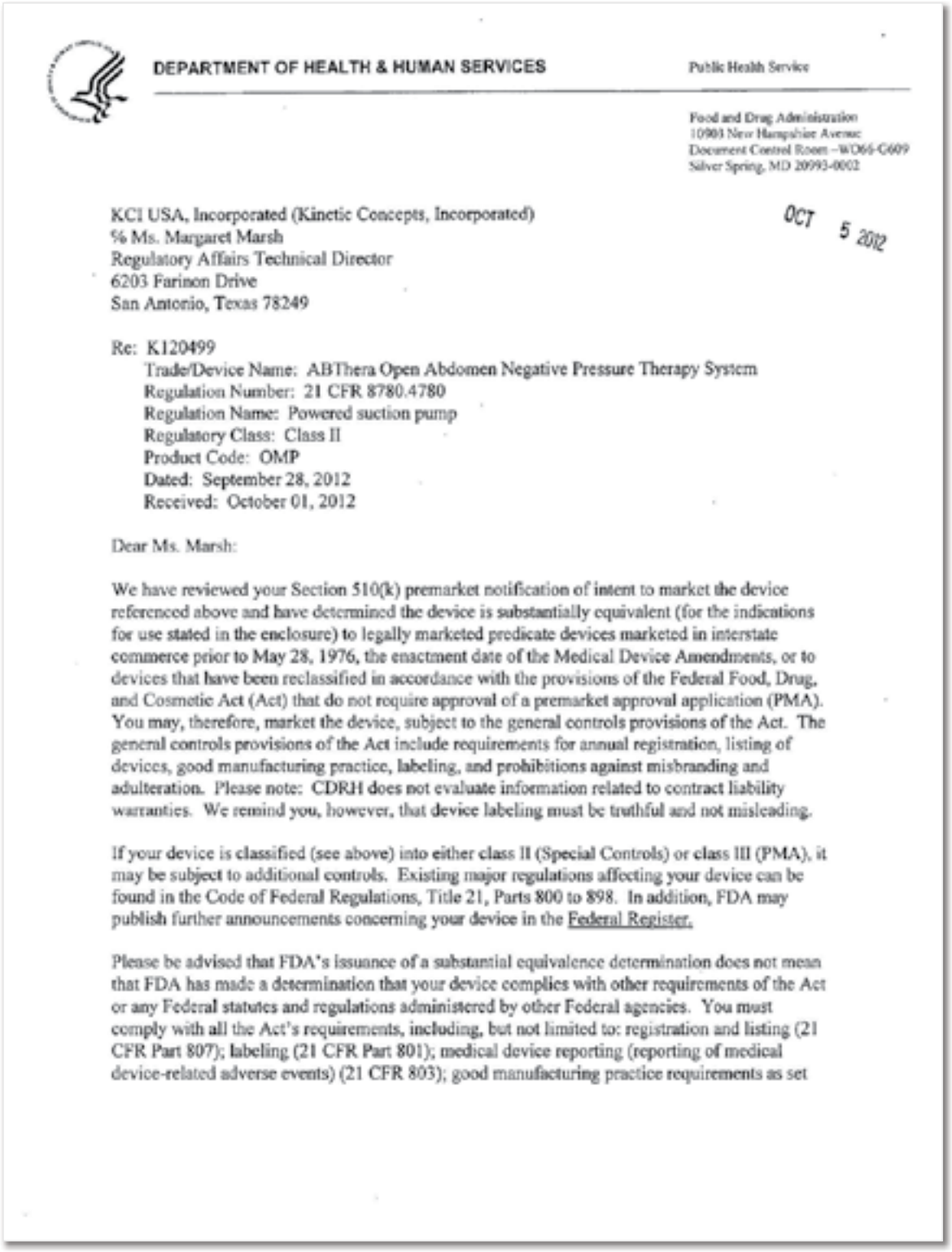
The next generation in temporary abdominal closure

Solventum™ AbThera™ Advance Open Abdomen Dressing

Solventum™ AbThera™ Advance Open Abdomen Dressing

The next generation of temporary abdominal closure, the AbThera Advance Dressing. This dressing includes a redesigned dressing configuration for drawing wound edges together, directly based upon the technology and success of Solventum™ AbThera™ Open Abdomen Negative Pressure Therapy.

Solventum™ AbThera™ Therapy is cleared under FDA clearance K120499 (see below). The AbThera Advance Dressing has been added to the Medical Device Listing database (see final page), and can be referenced by visiting the links shown.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KCI USA, Incorporated (Kinetic Concepts, Incorporated)
% Ms. Margaret Marsh
Regulatory Affairs Technical Director
6203 Farinon Drive
San Antonio, Texas 78249

OCT 5 2012

Re: K120499
Trade/Device Name: ABThera Open Abdomen Negative Pressure Therapy System
Regulation Number: 21 CFR 8780.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 28, 2012
Received: October 01, 2012

Dear Ms. Marsh:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

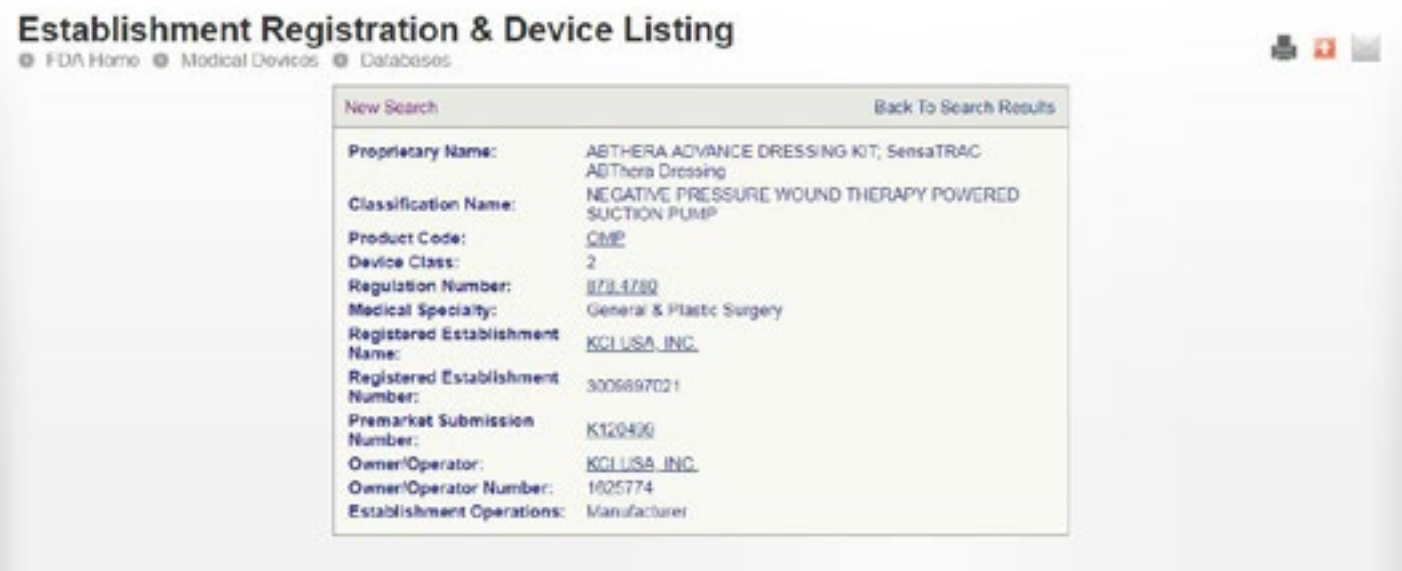
You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Solventum™ AbThera™ Advance Open Abdomen Dressing



Specifications

Solventum™ AbThera™ Advance Open Abdomen Dressing	
Sterile, latex free	
Shelf life	3 years at room temperature
Solventum™ AbThera™ Advance Perforated Foam	
Dimensions	380 mm (l) x 250 mm (w) x 16 mm (d)
Solventum™ AbThera™ Fenestrated Visceral Protective Layer	
Dimensions	665 mm x 802 mm
Encapsulated foam thickness	10 mm
Polyurethane layer thickness	160 microns

Ordering information

Item number	Description	Quantity
ABT1055	AbThera Advance Open Abdomen Dressing (Includes AbThera Fenestrated Visceral Protective Layer, AbThera Advance Perforated Foam, Solventum™ V.A.C.® Drape, and Solventum™ SensaT.R.A.C.™ Tubing)	5 per case

For use with negative pressure therapy provided by the Solventum™ V.A.C.® Ulta™ Therapy Unit.

For more information call your local Solventum Representative.

solventum

Solventum Advanced Wound Care
12930 IH10 W
San Antonio, TX 78249
USA

Phone 800-275-4524
Web Solventum.com

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

70-2013-1160-5 PRA-PM-US-03301 (09/21)