K022011

# 510(K) Summary

FEB 2 6 2003

# V.A.C.® Abdominal Dressing

1. **Name/Address of Submitter:** **Kinetic Concepts, Inc.**
   **8023 Vantage Drive**
   **San Antonio, TX 78265-9508**

2. **Contact Person:** **Judith Harbour, Manager Regulatory Affairs**

3. **Date Summary Prepared:** **June 7, 2002**

4. **Name of Device:** **V.A.C. Abdominal Dressing**

5. **Classification Name:** **Mesh, Surgical, Polymeric**
   **21 CFR 878.3300**
   **Class II**

6. **Predicate Devices:** **V.A.C. Plus (K992448)**
   **Ambulatory V.A.C. (971548)**
   **Wittman-Patch™ (K983753)**

7. **Description of Device and Intended Use**

The V.A.C. Abdominal Dressing will be provided in a kit to provide an easy, tailored method of applying the dressing in the open abdomen. The V.A.C. Abdominal Dressing is **supplied sterile, for single use only,** double-pouched and packaged as one kit.

Each V.A.C. Abdominal Dressing kit contains:

- One (1) internal contact layer
- Two (2) 16 mm outer layer polyurethane open-cell foam pieces
- Four (4) V.A.C. Drapes
- One T.R.A.C.™ pad assembly

**Indications**

The **V.A.C. Abdominal Dressing** is a specialty dressing 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 dressing 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.

The **V.A.C. Abdominal Dressing** is "substantially equivalent" to the **Star Temporary Wound Cover 510(k) No.K983753** (a.k.a. Wittman-Patch™).

Substantial equivalence for the V.A.C. Abdominal Dressing is based on the indications, intended use and technological features.

Material Biocompatibility issues have been addressed based upon biomaterial history. The material used in the KCI V.A.C. Abdominal Dressing are the same materials used for many years in the existing commercially available devices:

- V.A.C. previously cleared by the FDA in 1994 [510(k) No. K945062].
- Ambulatory V.A.C. previously cleared by the FDA in 1997 [510(k) No. K971548].
- V.A.C. Plus previously cleared by the FDA in 1999 [510(k) No. K992448]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Kinetic Concepts, Inc.
Judith A. Harbour
Manager, Regulatory Affairs
P. O. Box 659508
8023 Vantage Drive
San Antonio, Texas 78265-9508

Re: K022011
Trade/Device Name: V.A.C.® Abdominal Dressing
Regulation Number: 878.3300
Regulation Name: Mesh, Surgical, Polymeric
Regulatory Class: Class II
Product Code: FTL
Dated: December 23, 2002
Received: December 26, 2002

Dear Ms. Harbour:

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022011

Device Name: **V.A.C.® Abdominal Dressing**

Indications For Use:

The **V.A.C. Abdominal Dressing** is a specialty dressing 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 dressing 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.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K022011