510 (k) Summary
Sterile Equipment Covers

Date Prepared: August 30, 2005

Submitted by: Volcano Corp.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Michelle J. Badal, RAC
Regulatory Affairs Manager

Phone number: (916) 861-0287 or (800) 228-4728 ext. 287
Facsimile number: (916) 638-8112

Device Name: Sterile Equipment Covers

Classification name: **Class**
878.4370 Surgical drape and drape accessories II

Predicate Device:
The Sterile Equipment Covers are substantially equivalent to the MicroTek Equipment Drapes cleared under K050322 on May 17, 2005, Medline Band Bags and Equipment Covers cleared under K032065 on September 22, 2003, and United States Surgical Corporation cleared under K961699 on August 23, 1996. The Volcano Sterile Equipment Covers have the same *Intended Use* and utilizes the same *fundamental scientific technology* as that of the predicate devices.

Device Description:
Sterile Equipment Covers

Intended Use:
The Sterile Equipment Covers are intended to be used to cover medical equipment in order to maintain the sterile field. These covers are not intended to be used as patient drapes and have no patient contact.

Device Technological Characteristics and Comparison to Predicate Device:
The Sterile Equipment Covers uses the same fundamental scientific technology and has the same intended use and clinical applications as that of the predicate device.

Performance Data:
Sterilization validation testing was performed according to ANSI/AAMI/ISO 11135:1994. All requirements were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2005

Ms. Michelle J. Badal, RAC
Manager, Regulatory
Volcano Corporation
2870 Kilgore Road
Rancho Cordova, California 95670

Re: K052395
Trade/Device Name: Sterile Equipment Covers
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: November 23, 2005
Received: November 28, 2005

Dear Ms. Badal:

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.

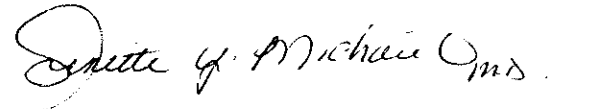
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K052395

Device Name: **Sterile Equipment Covers**

Indications For Use:

The Sterile Equipment Covers are intended to be used to cover medical equipment in order to maintain the sterile field. These covers are not intended to be used as patient drapes and have no patient contact.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____ (Part 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)

11/30/05

...on Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(k) Number: K052395