ATTACHMENT 2

K053495

Substantial Equivalence 510(k) Summary

Advance Medical Designs, Inc Equipment Slush Drape

To Whom It May Concern:

Date: 02/27/2006

Submitter/ Contact Name and Address
William Slevin
Advance Medical Designs, Inc.
1241 Atlanta Industrial Drive
Marietta, GA 30066

Tel: (770) 422-3125

Trade Name: Advance Medical Designs, Inc Equipment Slush Drape

Classification Name: Drape, Surgical

Common/ Usual Name: Equipment Slush Drape

Predicate Legally Marketed Device: MicroTek Equipment Drapes

Intended Use:

Advance Medical Designs equipment drapes are used to cover a variety of surgical and non-surgical equipment in various clinical settings. It is to be used in general and Endoscopic surgery for use with saline.

Description of the Device:

The Advance Medical Designs, Inc Equipment Drapes consist of polyurethane film that is cut and configured to specification. Packaged in a pouch to act as a sterile barrier. These equipment drapes are equivalent to other equipment drapes currently being marketed for the same intended use

Performance

The material used in this product has been tested to ASTM Method F 1671 for Viral Penetration and to 16 CFR Part 1610 for Flammability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Mr. William Slevin
Quality Assurance Regulatory Affairs
Advance Medical Designs, Incorporated
1241 Atlanta Industrial Drive
Marietta, Georgia 30066

Re: K053495
Trade/Device Name: Equipment Slush Drape
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: March 10, 2006
Received: March 13, 2006

Dear Mr. Slevin:

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

Enclosure

Indications for Use

510(k) Number (if known): K053495

Device Name: Slush Drape

Indications For Use:

Advance Medical Designs Slush Drapes are equipment covers used to cover a variety of surgical and non surgical equipment in various clinical settings. It is to be used in General and Endoscopic surgery for use with Saline.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K053495