MAY 17 2005 K050322

Premarket (510k) Summary

Submitter Information

Microtek Medical, Inc.
512 Lehmberg Road
Columbus, Mississippi 39702
662-327-1863
Contact person: Thomas Bonner
Date prepared: January 26, 2005

Device Name

Proprietary name: Microtek Medical, Inc., Equipment Drapes
Common name: Equipment Drapes.
CDRH Product Regulation: Surgical drape and drape Accessories (21 CFR, 878.4370)

Owner/Operator Number: 9009921

Establishment Registration Number: 1043582 (Microtek Medical, Inc.)

Classification: II

Statement of Substantial Equivalence

Microtek Medical, Inc. Equipment Drapes are equivalent to:

1. Medline band Bags and Equipment Drapes – K032065
2. Custom Medical Products Equipment Drapes – K931417

Description of Device

The Microtek Equipment Drapes consist of poly film and non-woven material, separately and in combination, manufactured to protect a variety of surgical and non-surgical equipment from contamination during various procedures throughout the clinical setting. These equipment drapes are similar to other equipment drapes currently being marketed for the same intended use.

Intended Use

The intended use of this device is to protect equipment from contamination during a variety of procedures throughout the clinical setting.

Materials

Most of the component materials used in the manufacture of these products are polyurethane film that is cut and configured to specification.

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Performance

These materials have been tested in other applications to ISO 10993-1 standards, however, since these products are non-patient contact, the material used in these products has been tested to ASTM Method F 1671 for Viral Penetration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Mr. Thomas B. Bonner
Vice President Regulatory Affairs/Quality Assurance
Microtek Medical, Incorporated
512 Lehmberg Road
Columbus, Mississippi 39702

Re: K050322
Trade/Device Name: Microter Medical, Inc. Equipment Drapes
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: April 19, 2005
Received: April 22, 2005

Dear Mr. Bonner:

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): K050322

Device Name: MICROTEK MEDICAL, INC. EQUIPMENT DRAPES

Indications For Use:

MICROTEK MEDICAL EQUIPMENT DRAPES ARE TO BE USED TO COVER A VARIETY OF SURGICAL AND NON-SURGICAL EQUIPMENT IN VARIOUS SETTINGS THROUGHOUT THE CLINICAL SETING. THESE DRAPES ARE USED TO PROTECT THE EQUIPMENT FROM CONTAMINATION DURING VARIOUS PROCEDURES.

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

Mark A. Murphy D

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

510(k) Number: K050322