K062899

Premarket (510k) Summary

Submitter Information

Microtek Medical, Inc.
512 Lehmberg Road
Columbus, Mississippi 39702
662-327-1863
Contact person: Thomas Bonner
JAN 25 2007
Date prepared: August 8, 2006

Device Name

Proprietary name: Microtek Medical, Inc., Gown/Toga
Common name: Surgical Apparel.
CDRH Product Regulation: Surgical Apparel (21 CFR, 878.4040)

Owner/Operator Number: 9009921

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

Classification: II

Statement of Substantial Equivalence

Microtek Medical, Inc. Gown/Toga is equivalent to:

1. DePuy Orthopedics gown/toga
2. Stryker gown/toga

Description of Device

The Microtek gown/toga consists of a non-woven material and woven cuff material manufactured to protect the wearer and patient from contamination during various procedures throughout the clinical setting. This gown/toga is similar to other gowns/togas currently being marketed for the same intended use.

Intended Use

The intended use of this device is to protect the health care professional and the patient from contamination during a variety of procedures throughout the clinical setting.

Materials

The component materials used in the manufacture of these products are Ahlstrom non-woven material (that maintains a premarket notification for the material by itself) that is cut/sewn and configured to specification. The gown also contains a woven gown cuff.

K062899

Performance

These materials have been tested alone and together to ISO 10993-1, ASTM Method F 1671 for Viral Penetration and flammability. The final finished product conforms to PB-70:2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas B. Bonner
Vice President
Microtek Medical, Incorporated
512 Lehmberg Road
Columbus, Mississippi 39702

JAN 25 2007

Re: K062899
Trade/Device Name: Microtek Surgical Gowns/TOGA
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: December 18, 2006
Received: December 28, 2006

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.

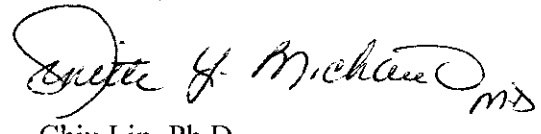
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K062899

Device Name: MICROTEK SURGICAL GOWN/TOGA

Indications For Use:

THE SURGICAL GOWN/TOGA IS INTENDED TO BE WORN BY OPERATING ROOM PERSONNEL DURING SURGICAL PROCEDURES TO PROTECT BOTH THE SURGICAL PATIENT AND OPERATING ROOM PERSONNEL FROM THE TRANSFER OF MICROORGANISMS, BODY FLUIDS, AND PARTICULATE MATERIAL.

Prescription Use _____ 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)

Sheila N. Murphy MD

K062899