K060200

Premarket (510k) Summary

Submitter Information

MAY 3 1 2006

Microtek Medical, Inc.
512 Lehmberg Road
Columbus, Mississippi 39702
662-327-1863
Contact person: Thomas Bonner
Date prepared: October 12, 2004

Device Name

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

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

Classification: II

Statement of Substantial Equivalence

Microtek Medical, Inc. Patient Warming Drape equivalent to:

1. Cincinnati Sub-Zero – Convective Air Warming Blankets
2. Nellcor (Tyco) Warmtouch Warming Blankets

Description of Device

The Microtek Patient Warming Drape consists of a non-woven surgical drape, similar to other surgical drapes currently being marketed, with the exception of an added channel (with holes) that is adhered to the drape and allows the passage of warm air.

Intended Use

Microtek Medical, Inc. Patient Warming Drape is intended to be used to provide patient warming during a variety of surgeries or procedures in the clinical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2006

MicroTek Medical, Inc.
% Mr. Thomas Bonner
512 Lehmberg Road
Columbus, Mississippi 39702

Re: K060200
Trade/Device Name: Microtek Medical, Inc. Warming Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical drape and drape accessories
Regulatory Class: II
Product Code: KKX
Dated: January 4, 2006
Received: February 10, 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.

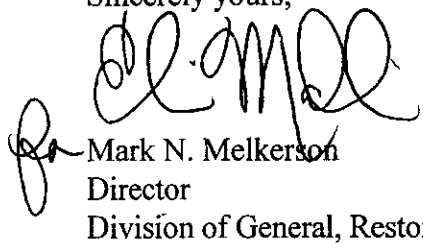
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060200

Device Name: Microtek Medical, Inc. Patient Warming Drape

Indications For Use:

Microtek Medical, Inc. Patient Warming Drape is intended to be used to provide patient warming during a variety of surgeries or procedures in the clinical setting.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 General, Restorative,
and Neurological Devices

510(k) Number K060200