K052668

510K SUMMARY

JUL 24 2006

Sponsor: OR Specific, Inc.
4651 36th St. #500
Orlando, FL USA

Proprietary/Trade Name: OR Specific Big Case Back Table Cover

Common/Usual Name: Equipment Drape

CDRH Product Regulation: Surgical Drape and drape Accessories (21 CFR 878.4370)

Device Class: Class II

Device/Product Code(s): KKX

Intended Use: The OR Specific, Inc. Big Case Back Table Cover is a single use, sterile packaged operating room equipment drape that is intended to provide and maintain a barrier against contamination between the OR Specific dual adjustable shelf operating room equipment tables and a variety of surgical and non surgical equipment during various procedures in the clinical and hospital operating room environment. In normal use as directed this product will not make direct contact with a patient. The drape is available 4 models to meet user requirements.

Part Number	Description
420HD-S	Big Case Back Table Cover (Heavy Duty) for 6' long Table (Sterile)
420-S	Big Case Back Table Cover (Standard) for 6' Long Table (Sterile)
419HD-S	Big Case Back Table Cover (Heavy Duty) for 5' Long Table (Sterile)
419-S	Big Case Back Table Cover (Standard) for 5' Long Table (Sterile)

Drapes are available in two lengths to fit 5 foot long and 6 foot long OR Specific dual adjustable shelf operating room equipment tables and each length of Drape is available in a Standard and Heavy Duty version differing in the thickness and composition of the poly film fluid barrier material used in the construction of the drape.

Device Description: The OR Specific, Inc. Big Case Back Table Cover is a single use, sterile packaged operating room equipment drape manufactured using poly film and non woven material, separately and in combination designed to protect a variety of Surgical and non Surgical equipment from Contamination during various procedures throughput the clinical and operating room setting. These equipment drapes are specifically designed to fit, attach to and cover the OR Specific Big Case Back Table and function in an identical manner to other equipment drapes currently being marketed for the same intended use.

2 sizes of these covers are available designed to function in conjunction with 2 different sizes of OR Specific Big Case Back Tables. In addition, the product is offered in either a standard or heavy duty version as follows.

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The drapes are packaged in heat sealed Medical grade paper and poly film pouches and ETO sterilized for convenient use in the clinical or hospital operating room environment.

The OR Specific Big Case Back Table Cover is manufactured from similar materials to the predicate devices and is packaged, sterilized and labeled in a similar manner. In addition, the indications for use are similar or identical to those of the predicate devices.

Potential Risks: The potential risks associated with this device are the same as with any surgical equipment drape. These include, but are not limited to:

Incorrect Application of the Drape to the equipment to be covered
Inadvertent contamination by the user during normal use
Inadvertent puncture of the cover resulting in contamination during normal use

Legally Marketed Predicate Devices:

Microtek Medical, Inc. Equipment Drapes K050322
Medline Band Bags and Equipment Drapes K0302065
Custom Medical Products Equipment Drapes K931417

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carl Knobloch
Official Correspondent
OR. Specific, Incorporated
4651 36th Street #500
Orlando, Florida 32811

JUL 24 2006

Re: K052668
Trade/Device Name: OR Specific, Inc Big Case Back Table Cover
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: July 5, 2006
Received: July 7, 2006

Dear Mr. Knobloch:

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): K052668

Device Name: OR Specific, Inc. Big Case Back Table Cover

Indications for Use: The OR Specific, Inc. Big Case Back Table Cover is a single use, sterile packaged operating room equipment drape that is intended to provide and maintain a barrier against contamination between the OR Specific dual adjustable shelf operating room equipment tables and a variety of surgical and non surgical equipment during various procedures in the clinical and hospital operating room environment. In normal use as directed this product will not make direct contact with a patient. The drape is available 4 models to meet user requirements.

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Prescription Use ______ (Part 21 CFR 801 Subpart D) AND/OR Over the Counter Use __X___ (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)

Sheila R. Murphy 2/24/06
(...ign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number K052668