K022483

FEB 0 3 2003

SECTION 2: 510(k) SUMMARY

ACTISORB* Silver 220 Antimicrobial Binding Dressing

Submitter's Name and Address

Johnson & Johnson Medical Limited
Gargrave
SKIPTON
North Yorkshire
BD23 3RX
United Kingdom

Contact Person

Patricia Flood.
Senior Project Manager, Regulatory Affairs
Johnson & Johnson Wound Management Worldwide
a Division of Ethicon, Inc.
Route 22 West P.O. Box 151
Somerville, NJ 08876

Telephone:	908-218-2893
Facsimile:	908-218-2595
e-mail:	pflood@ethus.jnj.com

Name of Medical Device

Classification Name:	Dressing, Wound
Common/Usual Name:	Antimicrobial Wound Dressing
Proprietary Name:	ACTISORB* Silver 220 Antimicrobial Binding Dressing

Substantial Equivalence

ACTISORB* Silver 220 Antimicrobial Binding Dressing is substantially equivalent to:

ACTISORB* Plus Activated Charcoal Dressing with Silver (K892851) manufactured by Johnson & Johnson Medical Ltd., Gargrave, SKIPTON, BD23 3RX, United Kingdom

ACTICOAT Calcium Alginate Dressing (K002896) manufactured by Westaim Biomedical Inc, One Hampton Road, Suite 320, Exeter, NH 03833

Device Classification

Antimicrobial wound dressings are currently unclassified by United States Food and Drug Administration's Center for Devices and Radiological Health.

Device Description

ACTISORB* Silver 220 Antimicrobial Binding Dressing is a sterile primary wound dressing, comprised of activated charcoal cloth, impregnated with silver, within a spun bonded nylon envelope. Within the dressing, there is 220mg silver per 100g activated charcoal cloth equating to 33µg of silver per square centimeter of cloth.

Indications for Use

ACTISORB* Silver 220 Antimicrobial Binding Dressing provides an effective barrier to bacterial penetration and for adsorbing offending odor resulting from wounds; the binding properties of the dressing trap bacteria, bacterial toxins and odor. ACTISORB* Silver 220 Antimicrobial Binding Dressing may help reduce infection in partial and full thickness wounds, including:

- pressure ulcers
- venous ulcers
- diabetic ulcers
- first and second-degree burns
- donor sites
- surgical wounds

ACTISORB* Silver 220 Antimicrobial Binding Dressing is suitable for use under compression bandaging.

Safety

Biocompatibility studies have demonstrated ACTISORB* Silver 220 Antimicrobial Binding Dressing to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 3 2003

Johnson & Johnson Medical Limited
c/o Ms. Patricia Flood
Senior Project Manager, Regulatory Affairs
Johnson & Johnson Wound Management Worldwide
a Division of Ethicon, Inc.
Route 22 West P.O. Box 151
Somerville, New Jersey 08876

Re: K022483
Trade Name: Actisorb* Silver 220 Antimicrobial Binding Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 25, 2002
Received: November 26, 2002

Dear Ms. Flood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K022483

Device Name: ACTISORB* Silver 220 Antimicrobial Binding Dressing

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Federal Law restricts, this device to sale by or on the order of a physician (or properly licensed practitioner).

Miriam C. Provost

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