K061308

CardinalHealth

JUN - 5 2006

Cardinal Health Inc.
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McGaw Park, Illinois 60085
847.473.1500
FAX: 847.785.2461

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Convertors® SMS Polyolefin Gowns, Breathable, Surgical Gowns, Breathable Surgical Gowns and O. R. Surgical Gowns

Manufacturer:	Cardinal Health Inc. One Butterfield Trail El Paso, Texas 79906
Regulatory Affairs Contact:	Lavenia Ford 1500 Waukegan Road MPWM McGaw Park, IL 60085
Telephone:	(847) 785-3323
Date Summary Prepared:	April 24, 2006
Common Name:	Convertors® SMS Polyolefin Gowns, Breathable Surgical Gowns with Breathable sleeves, Breathable Surgical Gowns and Optima Surgical Gowns
Classification:	Class II per 21CFR § 878.4040
Predicate Device:	Convertors® SMS Polyolefin Gowns, Breathable Surgical Gowns, Breathable Surgical Gowns and O. R Surgical Gowns
Description:	SMS polyolefin, the standard, fabric and poly-reinforced gowns are

comprised of a single layer of SMS polyolefin fabric. The fabric-reinforced gowns have an additional layer of SMS polyolefin fabric in the sleeve and body areas; the poly-reinforced gowns have an additional layer of polyolefin film in the sleeve and body areas.

The Breathable Surgical Gown with Breathable sleeves consists of an outer and inner layer of spunmelt polyolefin non-woven fabric with a middle layer of breathable monolithic film throughout the entire gown. The Breathable Sleeve Surgical Gown consists of sleeves containing an outer and inner layer of spunmelt polyolefin non-woven fabric with a middle layer of breathable monolithic film with a gown body comprised of spunmelt non-woven (SMS) with polyolefin-based film reinforcement.

The Breathable gown is comprised of a single layer of spunlace non-woven fabric (a blend of wood pulp and polyester) through the gown. An additional layer of breathable film adhesive laminated to the non-woven fabric in two configurations 1) through the entire gown and 2) in the front and sleeves.

The O. R. Surgical gowns are comprised of a wood pulp/polyester spunlaced fabric.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Convertors® SMS Polyolefin Gowns, Breathable, Surgical Gowns, Breathable Surgical Gowns and O. R. Surgical Gowns

Intended Use:

Surgical gowns are made from natural and synthetic materials that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of transfer of microorganisms body fluids and particulate material. The gown is a single use disposable device intended for repackaging and sterilization before use.

The single use product is a disposable non-sterile gown designed to be repackaged and sterilized prior to use. This product may be sterilized using Sterilization of Health Care Products-Requirements for Validation and Routine Control-Industrial moist Heat Sterilization and Ethylene Oxide following the Validation and Routine Control under ANSI/AMMI/ISO 11134 7 11135. For more information about sterilization of this product, contact Cardinal health, Inc.

Substantial Equivalence:	The Convertors® non-sterile gowns are substantially equivalent to the Convertors® SMS Polyolefin Gowns, Breathable Surgical Gowns, Breathable Surgical Gowns and O. R. Surgical Gowns have the same intended use as the current SMS Polyolefin Gowns, Breathable Surgical Gowns, Breathable Surgical Gowns and O. R. Surgical Gowns. - the intended use is the same - the performance attributes are the same
Summary of Testing	All materials used in the fabrication of this Convertors® SMS Polyolefin Gowns, Breathable Surgical Gowns, Breathable Surgical Gowns and O. R. Surgical Gowns have the same intended use that includes the same indication for use as the current SMS Polyolefin Gowns, Breathable Surgical Gowns, Breathable Surgical Gowns and O. R. Surgical Gowns were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, sensitization, and primary skin irritation. These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2006

Ms. Lavenia Ford
Manager, Regulatory Affairs
Cardinal Health 200 Incorporated
1500 Waukegan Road
McGaw Park, Illinois 60685

Re: K061308
Trade/Device Name: Convertors® SMS Polyolefin Gowns, Breathable Surgical Gowns Breathable Surgical Gowns and O.R. Surgical Gowns
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: April 24, 2006
Received: May 10, 2006

Dear Ms. Ford:

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

REVISED

CardinalHealth

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510(k) Number (if known): K061308

Device Name: Convertors® SMS Polyolefin Gowns, Breathable Surgical Gowns Breathable Surgical Gowns and O. R. Surgical Gowns

Indications For Use: Convertors®Surgical gowns are made from natural and synthetic materials that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material. The gown is a single use disposable device intended for repackaging and sterilization before use.

This single use product is a disposable non-sterile surgical gown designed to be repackaged and sterilized prior to use. This product may be sterilized using Sterilization of Health Care Products-Requirements for Validation and Routine Control-Industrial Moist Heat Sterilization and Ethylene Oxide following the Validation and Routine Control under ANSI/AMMI/ISO 11134 & 11135. For more information about sterilization of this product, contact Cardinal Health, Inc.

The exception for sterilization is that the SMS polyolefin reinforced gown, cannot under go steam sterilization. Steam sterilization may damage the impervious reinforcement on the gown. Ethylene Oxide is the only method of sterilization for this gown.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off) Number K061308