K061762

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CardinalHealth

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Trilaminate and Optima Drapes

Manufacturer:	Cardinal Health Inc. One Butterfield Trail El Paso, Texas 79906
Regulatory Affairs Contact:	Lavenia Ford
Telephone:	(847) 785-3323
Date Summary Prepared:	June 19, 2006
Common Name:	Convertors® Trilaminate and Optima Drapes
Classification:	Class II per 21CFR § 878.4370
Predicate Device:	Convertors® Trilaminate and Optima Drapes
Description:	The Trilaminate drapes are comprised of an outer and inner layer of polyolefin-based nonwovens with an inner layer of polyolefin-based film. The Optima drapes are comprised of a wood pulp/polyester spunlace fabric Several drapes have clear polyethylene side panels on either end of the drapes. Some of the drapes have clear fluid control pouches.

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Cardinal health
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SMDA REQUIREMENTS *(continued)*

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Trilaminate Drapes

Intended Use:

The Convertors® Trilaminate and Optima Drapes are devices intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

The single use product is a disposable non-sterile drape is designed to be repackaged and sterilized prior to use. The 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.

Substantial Equivalence:

The Convertors® Trilaminate and Optima Drapes are substantially equivalent to the Convertors® Trilaminate and Optima drape materials in that:

- the intended use is the same
- the performance attributes are similar

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Summary of testing:	All materials used in the fabrication of the Convertors® Trilaminate and Optima drapes 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 were also 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

AUG 0 1 2006

Ms. Lavenia Ford
Manager, Regulatory Affairs
Cardinal Health, Incorporated
Medical Products Manufacturing
1500 Waukegan Road
McGaw Park, Illinois 60085-6787

Re: K061762
Trade/Device Name: Convertors® Trilaminate and Optima Spunlace Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: July 21, 2006
Received: July 24, 2006

Dear Mr. 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 (240) 276-3150 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

CardinalHealth

Indications for Use

510(k) Number (if known): K061762

Device Name: Convertors®Trilaminate and Optima Spunlace Drapes

Indications for Use:

Convertors® Surgical drapes are made from natural and synthetic materials that are intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contaminated. The drape is a single use disposable device intended for repackaging and sterilization before use.

This single use product is a disposable non-sterile drape designed to be repackaged and sterilized prior to use. This product maybe 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 Steam sterilization is that the Trilaminate drapes, Trilaminate and Optima drapes with fluid control pouches, cannot undergo steam sterilization. Steam sterilization may cause the polyethylene in the film layer on the Trilaminate drape and the polyethylene in the fluid control pouch on these drapes to melt. Ethylene oxide is the only method of sterilization for these drapes.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] 8/14/06
[illegible] Sign-Off)
[illegible] of Anesthesiology, General Hospital,
[illegible] Control. Dental Devices
[illegible] Number K061762