K031301

CardinalHealth

OCT 1 5 2003

XIII. SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ESTEEM STERILE POLYISOPRENE SURGICAL GLOVES WITH COATING

Regulatory Affairs Contact:	Erica Sethi Cardinal Health 1500 Waukegan Road, MP-WM McGaw Park, IL 60085
Telephone:	(847) 785-3337
Date Summary Prepared:	4/7/03
Product Trade Name:	Undetermined
Common Name:	Surgical Glove
Classification:	Glove, Surgeon's
Predicate Devices:	Esteem Sterile Polyisoprene Surgical Gloves
Description:	Esteem Sterile Polyisoprene Surgical Gloves with Coating are formulated using Synthetic Rubber Latex. These are offered powder-free and sterile.
Intended Use:	Esteem Sterile Polyisoprene Surgical Gloves with Coating are intended for use in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.

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Substantial Equivalence:	Esteem Sterile Polyisoprene Surgical Gloves with Coating are substantially equivalent to Esteem Sterile Polyisoprene Surgical Gloves in that they provide the following characteristics: - same intended use - same sizes, product features, packaging - both made of Synthetic Rubber Latex using similar manufacturing process

Summary of Testing:

Test	Result
Primary Skin Irritation	Gloves are non-irritating.
Guinea Pig Maximization	Gloves do not display any potential for sensitization.
Ultimate Elongation & Tensile Strength	Gloves exceed requirements for rubber surgical gloves per ASTM D3577-01.
Barrier Defects	Gloves exceed requirements per 21 CFR §800.20 and ASTM D3577-01, AQL = 1.5.
Data/Test Method	Gloves meet powder level requirements for "Powder Free" designation using ASTM Standard D6124-00-Standard test method for residual powder on medical gloves. Results generated values below 2 mg of residual powder per glove.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Ms. Erica Sethi
Manager, Regulatory Affairs
Cardinal Heath
Medical Product and Services
1500 Waukegan Road Building WM
Mcgaw Park, Illinois 60085

Re: K031301
Trade/Device Name: Esteem Sterile Polyisoprene Powder Free Surgical Gloves with Coating
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: July 23, 2003
Received: July 24, 2003

Dear Ms. Sethi:

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.

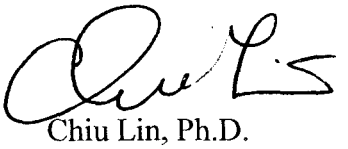
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594- 4618. 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,



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

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McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

Applicant: Cardinal Health

510(k) Number: K031301

Device Name: Esteem Sterile Polyisoprene Powder Free Surgical Gloves With Coating*

Indications For Use: These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive as well as non-invasive medical procedures requiring sterility.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

Patricia D. Patterson Branch Chief, 10/15/03

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

510(k) Number: K031301