

APR 27 2004

XIII. SUMMARY OF SAFETY AND EFFECTIVENESS**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
PROTEGRITY STERILE LATEX/NITRILE SURGICAL GLOVES WITH BROWN
COLORANT, COATING (CONTAINING CHITOSAN, PROVITAMIN B,
GLUCONOLACTONE AND GLYCEROL) AND PROTEIN LABELING CLAIM**

Regulatory Affairs Contact: Erica Sethi
Cardinal Health
1500 Waukegan Road, MP-WM
McGaw Park, IL 60085

Telephone: (847) 785-3337

Date Summary Prepared: 4/26/04

Product Trade Name: Undetermined

Common Name: Surgical Glove

Classification: Glove, Surgeon's

Predicate Devices: Protegrity Sterile Latex Surgical Gloves

Description: Protegrity Sterile Latex/Nitrile Surgical Gloves with brown colorant and coating are formulated using Natural Rubber Latex and Nitrile. These are offered powder-free and sterile. These latex gloves contain 50 micrograms or less of water extractable protein per gram.

Intended Use: Protegrity Sterile Latex/Nitrile Surgical Gloves with brown colorant and 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.

Substantial Equivalence: Protegrity Sterile Latex/Nitrile Surgical Gloves with brown colorant and coating are substantially equivalent to Protegrity Sterile Latex Surgical Gloves in that they provide the following characteristics:

- same intended use
- same sizes, product features, packaging
- both made of Natural Rubber Latex and Nitrile using similar manufacturing process

Summary of Testing:

| <u>Test</u> | <u>Result</u> |
|--|--|
| 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 D3577-01a ⁰² . |
| Barrier Defects | Gloves exceed requirements per 21 CFR §800.20 and ASTM D3577-01a ⁰² . |
| Data/Test Method | Gloves meet powder level requirements for "Powder Free" designation using ASTM Standard D6124-01-Standard test method for residual powder on medical gloves. Results generated values below 2 mg of residual powder per glove. |



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2004

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

Re: K033905

Trade/Device Name: Protegrity Sterile Latex/Nitrile Surgical Gloves with Proprietary Coating (Containing Chitosan, Provitamin B, Gluconolactone and Glycerol) with Protein Content Labeling Claim (50 Micrograms or Less) & Brown Coloring
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: March 4, 2004
Received: March 5, 2004

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



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FAX: 847.785.2460

Applicant: Cardinal Health

510(k) Number: K033905

Device Name: Undetermined

Device description: Protegrity Sterile Latex/Nitrile Surgical Gloves with brown colorant, proprietary coating (containing Chitosan, Provitamin B, Gluconolactone and Glycerol) and protein labeling claim (50 MICROGRAMS or less)

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. These latex gloves contain 50 micrograms or less of water extractable protein per gram.

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

Kevin Mahay
 (Division Sign-Off)
 Division of Anesthesiology, General Hospital,
 Infection Control, Dental Devices
 510(k) Number: K033905