K053272

CardinalHealth

JAN 5 2006

SUMMARY OF SAFETY AND EFFECTIVENESS
As required by §807.92(c)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
PROTEGRITY BLUE LATEX / NITRILE SURGICAL GLOVES WITH NEU-THERA

Regulatory Affairs Contact:	Amy Hoyd Cardinal Health 1500 Waukegan Road, MP-WM McGaw Park, IL 60085
Telephone:	(847) 578.2325
Fax:	(847) 785-2461
Date Summary Prepared:	11/14/05
Product Trade Name:	Protegrity Blue with Neu-Thera
Common Name:	Surgical Glove
Classification:	Glove, Surgeon's
Predicate Devices:	Cardinal Health's Protegrity Micro Sterile Latex Surgical Gloves (K001924)
Description:	Protegrity Blue Latex / Nitrile Surgical Gloves with Neu-Thera are formulated using Natural Rubber Latex. These are offered powder-free and sterile.
Intended Use:	Protegrity Blue Latex / Nitrile Surgical Gloves with Neu-Thera 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. These latex gloves contain 50 micrograms or less of water extractable protein per gram.

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continued

Substantial Equivalence:	Protegrity Blue Latex / Nitrile Surgical Gloves with Neu-Thera are substantially equivalent to Protegrity Micro Sterile Latex Surgical Gloves in that they provide the following characteristics: - same intended use - same sizes, product features - both made of Natural 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 D3577-01a^{e2}.
Barrier Defects	Gloves exceed requirements per 21 CFR §800.20 and ASTM D3577-01a^{e2}, AQL = 1.5.
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.

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SUMMARY OF SUBSTANTIAL EQUIVALENCE CON'T
510(k) S. E. DECISION SUMMARY
PROTEGRITY MICRO STERILE LATEX SURGICAL GLOVES (K001924)
vs.
PROTEGRITY BLUE LATEX / NITRILE SURGICAL GLOVES WITH NEU-THERA

QUESTION	SUMMARY RESPONSE	REFERENCE
3. Does new device have same indication statements?	**YES**: Protegrity Blue Latex Surgical Glove with Neu-Thera has the identical intended use as Protegrity Micro Sterile Latex Surgical glove. Both are intended to be worn by operating room personnel to protect a surgical wound from contamination.	Page 16-17
5. Does new device have same technological characteristics?	**YES**: The answer is Yes for the following: a) Coated Gloves and Protegrity Gloves are made from a similar latex slurry and coagulant formulation. b) Both gloves are similar with regard to design, namely size, physical form and hand specific nature. c) Both gloves are comparable with respect to the requirements outlined in ASTM D3577-01a^{e2}. d) Both gloves are sterile, powder-free and have the protein labeling claim. e) Both gloves are lubricated with CPC, silicone. f) Both gloves have beaded cuffs. g) Both gloves are made using triple dipping technology that includes a nitrile coating. **NO**: The answer is No for the following: a) The colorants used in the manufacturing process of the two products are different. b) Neu-Thera Gloves are coated with Polymeric Amino Sugar, Deacetylated Chitin (Hydagen CMF), Citric Acid, Glycerol, D-Sorbitol, Provitamin B-5 (Ritapan DL) , Glucono-delta-lactone (Glucono-d-lactone), Triethyl Citrate (Hydagen CAT), Sodium Citrate Dihydrate and Ammonium salts of alkyl phosphate (Darvan L)	Page 16-17 and Attachment J Pages 16-17 and Attachment J
7. Are the descriptive characteristics precise enough to ensure equivalency?	**YES:** The physical testing performed indicates that the product is acceptable. The predicate device comparison table outlines the critical parameters of both gloves. Given the products intended use, the descriptive characteristics adequately demonstrate equivalency.	Pages 16-17 and Attachment J

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MANUFACTURE'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notifications for tier 1 devices)

STATEMENT OF INDICATIONS FOR USE:

Protegrity Blue Latex / Nitrile Surgical Gloves with Neu-Thera are designed for use during invasive and non-invasive medical procedures requiring sterility. They are designed to be worn by operating room personnel to protect a surgical wound from contamination. These latex gloves contain 50 micrograms or less of water extractable protein per gram.

CLAIMS:

Protegrity Blue Latex / Nitrile Surgical Gloves with Neu-Thera:

Sterile, powder-free, for single use only, contains natural rubber latex

* Sterile, powder-free, for single use only
* This latex glove contains 50 micrograms or less of total water extractable protein per gram
* Glove provides superior wet donning properties for easy donning

This notification contains all of the information required by 21 CFR §807.87.
A completed copy of the "Premarket Notification 510(k) Reviewer's Screening Checklist" is included with this submission.

The subject device conforms to the following voluntary and mandatory standards:
Good Manufacturing Practices, ASTM Standard D3577-99.

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and intended use are equivalent.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR §807.87 (j)).

MANUFACTURER: CARDINAL HEALTH

OFFICIAL CORRESPONDENT: Amy J. Hoyd (signature)

Amy Hoyd (printed name)
TITLE: Regulatory Affairs Manager
DATE: 28 December 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 5 2006

Cardinal Health
C/O Ms. Amy Hoyd
Regulatory Affairs Manager
Medical Products and Services
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K053272
Trade/Device Name: Protegrity Sterile Latex/Nitrile Surgical Gloves with Blue Colorant and Neu-Thera Proprietary Coating (Containing Chitosan, ProVitamin B5, Gluconolactone and Glycerol) and Protein Labeling Claim of 50 Micrograms or Less
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: November 16, 2005
Received: December 13, 2005

Dear Ms. Hoyd:

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

CardinalHealth

1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

3.0 Indications for Use Statement

510(k) Number: (if known): K053272

Device Name:	Protegrity Sterile Latex/Nitrile Surgical Gloves with blue colorant and Neu-Thera proprietary coating (containing Chitosan, ProVitamin B5, Gluconolactone and Glycerol) and protein labeling claim of 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 gloves contain 50 micrograms or less of water extractable protein per gram.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

1/4/06

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Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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