



MAY - 7 2004

KO33789

### **XIII. SUMMARY OF SAFETY AND EFFECTIVENESS**

#### **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Latex Powder-Free Examination Glove with tan color, proprietary coating (containing Provitamin B, Gluconolactone and Glycerol), protein labeling claim and chemotherapy labeling claim**

**Applicant/Sponsor:** Cardinal Health  
1500 Waukegan Road  
McGaw Park, IL 60085

**Regulatory Affairs Contact:** Erica Sethi  
Cardinal Health  
1500 Waukegan Road, Bldg. WM  
McGaw Park, IL 60085

**Telephone:** (847) 785-3337

**Date Summary Prepared:** 5/4/04

**Product Trade Name:** Undetermined

**Common Name:** Examination Glove

**Classification:** Patient Examination Glove

**Predicate Devices:** Latex Powder-Free Examination Gloves

**Description:** Latex Powder-Free Examination Glove with tan color, proprietary coating (containing Provitamin B, Gluconolactone and Glycerol), protein labeling claim and chemotherapy labeling claim are formulated using Latex and offered powder-free.

**Intended Use:** These examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. These latex gloves contain 50 micrograms or less of total water extractable protein per gram.

**Substantial Equivalence:** Latex Powder-Free Examination Glove with tan color, proprietary coating (containing Provitamin B, Gluconolactone and Glycerol), protein labeling claim and chemotherapy labeling claim are substantially equivalent to Cardinal Health's Latex Powder-Free Examination Gloves in that they provide the following characteristics:

- same intended use
- both made of Latex
- both offered beaded and powder-free

**Summary of Testing:**

<u>Test</u>	<u>Result</u>
Primary Skin Irritation	Gloves show no irritation.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Tensile Strength	Gloves meet or exceed requirements per ASTM D3578-01a <sup>02</sup> .
Barrier Defects	Gloves meet or exceed requirements per 21 CFR§800.20 and ASTM D3578-01a <sup>02</sup> .
Chemotherapy testing	Tested for chemotherapy drugs using ASTM F739-99a



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Cardinal Health  
Ms. Erica Sethi  
Manager, Regulatory Affairs  
Medical Product and Services  
1500 Waukegan Road Building WM  
McGaw Park, Illinois 60085-6787

Re: K033789

Trade/Device Name: Latex Powder-Free Examination Glove with Tan Color,  
Proprietary Coating (Containing Provitamin B, Gluconolactone and Glycerol),  
Protein Labeling Claim and Chemotherapy Labeling Claim  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LZC  
Dated: April 8, 2004  
Received: April 9, 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



CardinalHealth

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Ren Muley

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

510(k) Number: K033789

Page 1 of 1

Applicant: Cardinal Health

510(k) Number: K033789

Device Name: Latex Powder-Free Examination Glove with tan color, proprietary coating (containing Provitamin B, Gluconolactone and Glycerol), protein labeling claim and chemotherapy labeling claim

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

or

Over-The Counter Use X