JUL - 5 2007

21.0 Summary

[1] 510(k) Summary of Safety and Effectiveness Information

[2] Submitter: Glormed Colombia S.A.
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Date: June 14, 2007

[3] Trade name: (Multiple private labels)
Common name: Powder-Free Examination Glove, Vinyl
Classification name: Patient examination gloves, powder-free
(per proposed 21 CFR §880.6251)

[4] The predicate device is a Class I, powder-free vinyl exam glove 80LYZ that meets all of the requirements of ASTM D 5250-00, *"Standard Specification for Poly(vinyl chloride) Gloves for Medical Application."*

[5] The powder-free vinyl exam glove meets the current specifications of ASTM D 5250-00, *"Standard Specification for Poly(vinyl chloride) Gloves for Medical Application."*

[6] A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner against potentially infectious materials.

[7] Applicant's device comparison with FDA required technological characteristics:

Characteristics	Standard
Dimensions	Meets ASTM D 5250-00
Physical Properties	Meets ASTM D 5250-00
Freedom from pinholes	Meets ASTM D 5250-00 and ASTM D 5151-99
Powder Free	Meets ASTM D 6124-00 and ASTM D 5250-00

Premarket Notification 510(k) K071022 Powder-Free Vinyl Examination Glove

Biocompatibilty: (based on ISO 10993)

Cytotoxicity – Agar Diffusion	Passed
Primary Skin Irritation	Passed
Guinea Pig Sensitization	Passed

Measured Parameter of Applicant Device Compared to Standard:

ASTM D5250 / ASTM D 6124 Requirement		Applicant Device Specification	
Width (mm)			
Small	85	85 +/- 5	
Medium	95	95 +/- 5	
Large	105	105 +/- 5	
X-Large	115	115 +/- 5	
Length (mm) – all sizes	230 minimum	250 +/- 10	
Thickness (mm) – all sizes			
Finger	0.05 minimum	0.05 minimum	
Palm	0.08 minimum	0.1 minimum	
Physical Testing			
Tensile Strength		Before Aging	After Aging
(in MPa)	9 minimum	9 min	9 min
Ultimate Elongation			
(in %)	300% minimum	300% min	300% min
Water Leak Test	AQL 2.5, Level I	AQL 2.5, Level I	

Both its intended use and physical characteristics is equivalent to legally marketed vinyl powder-free examination gloves. It is substantially equivalent to gloves approved as Glormed International's vinyl powder-free glove K983494.

[8] The performance test data that support a determination of substantial equivalence are described above in Section 7.

[9] Clinical data are not needed for examination gloves.

[10] (Multiple private labels) Powder-Free Vinyl Examination Glove is safe and effective and will perform according to glove performance standards referenced in Section 7 above, thereby meeting ASTM D5250 and D6124 standards, FDA requirements, pinhole AQL requirement, and labeling claims for the product. Consequently, this patient examination glove is substantially equivalent to currently marketed patient examination gloves.

[11] This summary will include any additional safety and effectiveness information reasonably deemed necessary by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2007

Glormed Colombia S.A.
C/O Mr. Sam Kao
Project Manager
KalMed Supply
2700 North Main Street Suite 506
Santa Ana, California 92705

Re: K071022
Trade/Device Name: Vinyl Patient Examination Glove, Powder-Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: June 14, 2007
Received: June 15, 2007

Dear Mr. Kao:

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.

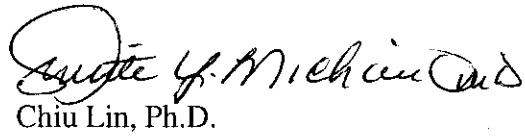
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K071022

Device Name: Vinyl Patient Examination Glove, Powder-Free

Indications For Use:

Based upon 21 CFR §880.6251 "Patient examination glove, powder-free"

A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner against potentially infectious materials.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071022