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K001924

# XIV. SUMMARY OF SAFETY AND EFFECTIVENESS

Allegiance

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
## COATED STERILE LATEX POWDER-FREE SURGICAL GLOVES

| | |
|---|---|
| Manufacturer: | Allegiance Healthcare Sdn. Bhd.<br>Plot 87, Kampung Jawa<br>11900 Bayan Lepas<br>Penang, West Malaysia |
| Regulatory Affairs Contact: | Erica Sethi<br>Allegiance Healthcare Corporation<br>1500 Waukegan Road, MP-WM<br>McGaw Park, IL 60085 |
| Telephone: | (847) 785-3337 |
| Date Summary Prepared: | 6/16/00 |
| Product Trade Name: | Undetermined |
| Common Name: | Surgical Glove |
| Classification: | Glove, Surgeon's |
| Predicate Devices: | Protegrity Sterile Latex Powder-Free Surgical Gloves |
| Description: | Coated Sterile Latex Powder-free Surgical gloves are formulated using natural rubber latex and are coated with a nitrile coating. These are offered powder-free and sterile. |
| Intended Use: | Coated Sterile Latex Powder-Free Surgical Gloves 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. |

K001924



Substantial Equivalence: Coated Sterile Latex Powder-Free Surgical Gloves are substantially equivalent to Protegrity Sterile Latex Powder-Free Surgical Gloves in that they provide the following characteristics:

- same intended use
- same sizes, configuration, packaging
- both made of natural rubber latex with a nitrile coating
- same tensile strength and thickness profiles

Summary of Testing:

| Test | Result |
|---|---|
| Primary Skin Irritation | Gloves show no irritation. |
| Guinea Pig Maximization | Gloves do not display any potential for sensitization. |
| Ultimate Elongation & Tensile Strength | Gloves exceed requirements for rubber surgical gloves per ASTM D3577-99. |
| Barrier Defects | Gloves exceed requirements per 21 CFR §800.20, AQL = 2.5. |
| Data/Test Method | Gloves meet powder level requirements for "Powder Free" designation using ASTM Standard D6124-97-Standard test method for residual powder on medical gloves. Results generated values below 2 mg of residual powder per glove. |
| Protein Labeling Claim | This latex glove contains 50 micrograms or less of total water extractable protein per gram. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 4 2000

Ms. Erica Sethi
Manager, Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road, Building MP-WM
McGaw Park, Illinois 60085

Re: K001924
Trade Name: Coated sterile Latex Powder-Free Surgical Gloves with Protein Content Labeling Claim (50 Microgram or Less)
Regulatory Class: I
Product Code: KGO
Dated: June 15, 2000
Received: June 23, 2000

Dear Ms. Sethi

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Allegiance

*Allegiance Healthcare Corporation*
*1500 Waukegan Road*
*McGaw Park, Illinois 60085-6787*
*847.473.1500*
*FAX: 847.785.2460*



Applicant: Allegiance Healthcare Corporation

510(k) Number: K001924

Device Name: Coated Sterile Latex Powder-Free Surgical Gloves WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)

Indications For Use: These gloves are intended for use 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. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.

(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 X
(Per 21 CFR 801.109)

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001924