

K983962

JAN 8 1999

#### XIV. SUMMARY OF SAFETY AND EFFECTIVENESS



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

**Manufacturer:** Allegiance Healthcare Sdn. Bhd.  
Plot 87, Kampung Jawa  
11900 Bayan Lepas  
Penang, West Malaysia

**Regulatory Affairs Contact:** Erica Sethi  
Allegiance Healthcare Corporation  
1500 Waukegan Road, Bldg. K  
McGaw Park, IL 60085

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

**Date Summary Prepared:** October 21, 1998

**Product Trade Name:** Ultrafree Textured Sterile Latex Powder-Free Surgical Gloves

**Common Name:** Surgical Glove

**Classification:** Glove, Surgeon's

**Predicate Devices:** Ultrafree Sterile Latex Powder-Free Surgical Gloves

**Description:** The Ultrafree Textured Surgical gloves are formulated using natural rubber latex and offered powder-free and sterile.

**Intended Use:** Ultrafree Textured 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.

**Substantial Equivalence:** The Ultrafree Textured Sterile Latex Powder-Free Surgical Gloves are substantially equivalent to Ultrafree 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
- same tensile strength and thickness profiles

**Summary of Testing:**

<u>Test</u>	<u>Result</u>
Primary Skin Irritation	Biocompatibility tests successfully performed on Ultrafree Surgical Gloves were considered applicable to Ultrafree Textured Surgical Glove since they are made using the same latex formulation and manufacturing process. Gloves do not display any potential for irritation.
Systemic Toxicity	Gloves do not elicit any toxic reactions to acute application.
Intracutaneous Reactivity	Gloves show no reactivity.
Hemocompatibility	Gloves are hemocompatible exhibiting no lysis.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Ultimate Elongation & Tensile Strength	Gloves meet or exceed requirements for rubber surgical gloves per ASTM D3577-91.
Barrier Defects	Gloves meet or 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Erica Sethi  
Allegiance Healthcare Corporation  
1500 Waukegan Road, Building K  
McGaw Park, Illinois 60085

Re: K983962  
Trade Name: Ultrafree Textured Sterile Latex Powder-Free  
Surgical Gloves  
Regulatory Class: I  
Product Code: KGO  
Dated: December 16, 1998  
Received: December 17, 1998

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 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). 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.

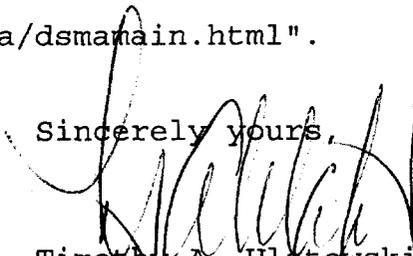
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/dsmanain.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



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Applicant: Allegiance Healthcare Corporation

510(k) Number: K983962

Device Name: Ultrafree Textured Sterile Latex Powder-Free Surgical Gloves

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

or

Over-The Counter Use

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number

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