

## XIV. SUMMARY OF SAFETY AND EFFECTIVENESS



### 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS ULTRADERM STERILE LATEX SURGICAL GLOVES WITH PROTEIN CONTENT LABELING CLAIM

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, MP-WM  
McGaw Park, IL 60085

Telephone: (847) 785-3337

Date Summary Prepared: 3/26/99

Product Trade Name: Ultraderm Sterile Latex Surgical Gloves with Protein Content Labeling Claim

Common Name: Surgical Glove

Classification: Glove, Surgeon's

Predicate Devices: Ultraderm Sterile Latex Surgical Gloves

Description: Ultraderm Surgical gloves are formulated using natural rubber latex and contain 50 micrograms or less of total water extractable protein per gram..

Intended Use: Ultraderm Sterile Latex Surgical Gloves with Protein Content Labeling Claim 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: Ultraderm Sterile Latex Surgical Gloves with Protein Content Labeling Claim are substantially equivalent to Ultraderm Sterile Latex Surgical Gloves in that they provide the following characteristics:

- same intended use
- same sizes, configuration, packaging
- both made of natural rubber latex using same formulation and manufacturing process
- same tensile strength and thickness profiles

Summary of Testing:

<u>Test</u>	<u>Result</u>
Primary Skin Irritation	Biocompatibility tests were successfully performed on Ultraderm Surgical Gloves with Protein Content Labeling Claim. 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 D3577-98.
Barrier Defects	Gloves meet or exceed requirements per 21 CFR §800.20, AQL = 2.5.
Data/Test Method	Gloves meet requirements for protein claim of 50 micrograms or less of water extractable protein per gram using ASTM Lowry test method (ASTM 5712-95).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 13 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Erica Sethi  
Manager, Regulatory Affairs  
Allegiance Healthcare Corporation  
1500 Waukegan Road  
McGraw Park, IL 60085

Re: K991205  
Trade Name: Ultraderm Sterile Latex Powdered Surgical  
Gloves With Protein Content Labeling Claim (50 micrograms  
or less)  
Regulatory Class: I  
Product Code: KGO  
Dated: August 5, 1999  
Received: August 9, 1999

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 (Pre-market 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 pre-market notification submission does not affect any

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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

K991205



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Applicant: Allegiance Healthcare Corporation  
510(k) Number: K991205  
Device Name: Ultraderm Sterile Latex 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 \_\_\_\_\_  
(Per 21 CFR 801.109)

or

Over-The Counter Use X

Chin S. Lin  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K991205