K011721

AUG 1 4 2001

XIII. SUMMARY OF SAFETY AND EFFECTIVENESS

Allegiance

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
POWDER-FREE STERILE SYNTHETIC SURGICAL GLOVES

Regulatory Affairs Contact:	Erica Sethi Allegiance Healthcare Corporation 1500 Waukegan Road, MP-WM McGaw Park, IL 60085
Telephone:	(847) 785-3337
Date Summary Prepared:	5/25/01
Product Trade Name:	Esteem Sterile Polyisoprene Surgical gloves
Common Name:	Surgical Glove
Classification:	Glove, Surgeon's
Predicate Devices:	Duraprene Powder-Free Sterile Synthetic Surgical Gloves
Description:	Powder-Free Sterile Synthetic Surgical gloves are formulated using Synthetic Rubber Latex. These are offered powder-free and sterile.
Intended Use:	Powder-Free Sterile Synthetic 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.

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Substantial Equivalence:	Powder-Free Surgical Gloves are substantially equivalent to Duraprene Powder-Free Sterile Synthetic Surgical Gloves in that they provide the following characteristics: - same intended use - same sizes, product features, packaging - both made of Synthetic Rubber Latex using similar manufacturing process

Summary of Testing:

Test	Result
Intracutaneous Reactivity	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 D3577-00.
Barrier Defects	Gloves exceed requirements per 21 CFR §800.20 and ASTM D3577-00, AQL = 1.5.
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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2001

Ms. Erica Sethi
Manager of Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K011721
Trade/Device Name: Powder-Free Sterile Synthetic Polyisoprene Surgical Gloves
Regulation Number: 878.4460
Regulatory Class: I
Product Code: KGO
Dated: May 4, 2001
Received: June 4, 2001

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 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,

Patricia Cucinotta for

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

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FAX: 847.785.2460

Applicant: Allegiance Healthcare Corporation

510(k) Number: K011721

Device Name: Powder-Free Sterile Synthetic Surgical Gloves (POLYISOPRENE)

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

(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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011721