K971381

Allegiance

JUL - 9 1997

510(k) SUMMARY K971381

Manufacturer:	Allegiance Healthcare Corporation Route 35 West Eaton, Ohio 45320
Regulatory Affairs Contact:	Maryalice Smith 1500 Waukegan Road, Bldg. K McGaw Park, IL 60085
Telephone:	(847) 785-3322
Date Summary Prepared:	March, 1997
Product Trade Name:	Powder-Free Duraprene™ Sterile Synthetic Surgical Gloves
Common Name:	Surgical Glove
Classification:	Glove, Surgical
Predicate Devices:	Duraprene™ Sterile Synthetic Surgical Gloves
Description:	The Duraprene Sterile Synthetic Surgical Gloves are formulated using neoprene and offered sterile.
Intended Use:	Powder-Free Duraprene™ Sterile Synthetic Surgical Gloves are intended for use in sterile environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive surgical procedures and non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination. These gloves are constructed from synthetic materials. They are intended to provide an alternative to wearers and patients sensitive to natural rubber.

Substantial Equivalence:

The Powder-Free Duraprene™ Sterile Synthetic Surgical Gloves are substantially equivalent to powdered Duraprene™ Surgical Gloves in that they provide the following characteristics:
- intended use
- size, configuration, packaging
- made of synthetic materials
- tensile strength and thickness profiles

Summary of Testing:

Test	Result
Intracutaneous Reactivity	Glove does not elicit irritation following intradermal injection of extracts.
Kligman Maximization Sensitization	Glove does not display potential to produce skin sensitization.
USP Mouse Systemic Test	No systemic response was observed.
Ultimate Elongation & Tensile Strength	Glove meets or exceeds requirements for rubber surgical gloves per ASTM D3577-91.
Barrier Defects	Glove meets or exceeds requirements per 21 CFR §800.20, AQL = 2.5 and ASTM D3577-91, AQL=1.5.
Data/Test Method	Gloves meet powder level requirements for "Powder Free" designation using the vacuum filtration method plus a negative iodine test. Results generated values below the 2mg/glove cornstarch level including negative iodine test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Maryalice Smith
Regulatory Affairs Manager
Allegiance Healthcare Corporation
1500 Waukegan Road, Bldg. K
McGaw Park, Illinois 60085

Re: K971381
Trade Name: Powder-Free Duraprene Sterile Synthetic Surgical Gloves
Regulatory Class: I
Product Code: KGO
Dated: April 10, 1997
Received: April 14, 1997

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Dear Ms. Smith:

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 current Good Manufacturing Practice requirement, 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) 594-4618. 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
847.473.1500

Applicant: Allegiance Healthcare Corporation

510(k) Number (if known): K971381

Device Name: Powder-Free Duraprene™ Sterile Synthetic Surgical Gloves

Indications For Use: These gloves are intended for use in sterile environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive surgical procedures as well as non-invasive activities requiring sterility. They are designed 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

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971381

Prescription Use _____ or Over-The Counter Use ✓
(Per 21 CFR 801.109)