



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 #K
McGraw Park, Illinois 60085

JUL 28 1997

Re: K972291
Trade Name: Allegiance Non Sterile Powder Free
Latex Examination Glove With Protein Labeling Claim
Regulatory Class: I
Product Code: LYY
Dated: May 28, 1997
Received: June 19, 1997

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 \

Page 2 - Ms. Smith

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 Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1600
FAX: 847.785.2460

Page 1 of 1

Applicant: Allegiance Healthcare Corporation

510(k) Number (if known) K972291

Device Name: Non Sterile Powder-Free Latex Examination Gloves with a Protein Label Claim

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

(Division Sign-Off) [Signature]
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K972291

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

JUL 28 1997

XIII. 510(k) SUMMARY

K972291

- Applicant:** Allegiance Healthcare Corporation
1500 Waukegan Road, Bldg. K
McGaw Park, IL 60085
- Contact Person:** Maryalice Smith, (847) 785-3322
2. **Manufacturing and Chlorination Facility:** Allegiance Healthcare Sdn. Bhd.
Plot 87 Kampung Jawa
Bayan Lepas, Penang, West Malaysia 11900
3. **Chlorination Facility:** Digitcare Corporation Sdn. Bhd.
Lot 3 Jalan 1/113A,
Batu 4 1/2, Jalan Kelang Lama,
Kilang Yee Seng,
58000 Kuala Lumpur, Malaysia
- Maxi Support Sdn. Bhd.
99-L Lorong Perak 4, Kawasan Perusahaan Mergong.
05150 Alor Setar,
Kedah Darul Aman, Malaysia.
5. **The Powder-Free Non-Sterile Latex Examination Gloves, with a protein label claim, are substantially equivalent to the Flexam Powdered Non-Sterile Examination Glove in regard to the material, design, physical characteristics and intended use.**

A battery of performance tests were conducted, verifying the acceptability of this product for its intended use. The Powder-Free Non-Sterile Latex Examination Gloves with a protein label claim were subjected to biological evaluation. The gloves passed the acceptability criteria for primary skin irritation, intracutaneous reactivity and skin sensitization as outlined in ISO 10993 1/USP XXIII. In addition, the product was found acceptable based on chemical analysis of materials. Test methods for inspection of gloves and for chemical, biocompatibility and physical testing are listed in *Appendix C* of this document. The leak test method employed is the FDA 1000 mL test method which is described in 21 CFR §800.20.

This product meets the requirement specified in ASTM Standard Specification for Rubber Examination Gloves D3578-95.

XIII. 510(k) SUMMARY (Con't)

7. Physical Characteristics:

See Appendix C, Page 37 for detailed summary

	33 MPa	28 MPa
	905%	966%

8. This product will be marketed non-sterile in sizes small, medium, large and extra large.. Dimensions of the medium glove is as follows:

	Powder Free Low Examination	ASTM 9578
Size: Medium		
Length (cm)	min. 23.0	min. 23.0
Width (cm)	9.8-10.0	8.5-10.5
Thickness (cm)		
Cuff	0.13 mm (min.)	NA
Palm	0.19 mm (min.)	0.08 mm (min.)
Finger	0.20 mm (min.)	0.08 mm (min.)

9. Powder manufactured by Roquette America, Inc., Keokuk, Iowa 52632, (NDA 85-356) is used during manufacture. Powders which may be present due to the manufacturing process are removed through chlorination. The Quality Assurance method is included in *Appendix E*. No special claims are made for this product and the product is not expiration dated.



XIV. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS POWDER-FREE NON-STERILE LATEX EXAMINATION GLOVES WITH A PROTEIN LABEL CLAIM

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

Regulatory Affairs Contact: Maryalice Smith
1500 Waukegan Road, Bldg. K
McGaw Park, IL 60085

Telephone: (847) 785-3322

Date Summary Prepared: May, 1997

Product Trade Name: Powder-Free Non-Sterile Latex Examination Gloves with a Protein Label Claim

Common Name: Patient Examination Glove

Classification: Glove, Examination (Latex)

Predicate Devices: Flexam Examination Gloves (latex).

Description: The Powder Free Non Sterile Examination gloves with a protein label claim are formulated using in-house compounded latex and offered non-sterile.

Intended Use: Powder-Free Non-Sterile Latex Examination gloves with a protein label claim. Gloves are a disposable device intended for medical purposes that are worn on the examiner's hand or finger to prevent contamination between patient and examiner.



XIV. STATEMENT OF SAFETY AND EFFECTIVENESS

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (con't)
POWDER-FREE NON-STERILE LATEX EXAMINATION GLOVES WITH A
PROTEIN LABEL CLAIM**

Substantial Equivalence

Powder Free Non-Sterile Examination Gloves with a protein label claim are substantially equivalent to the Flexam Non-Sterile Examination Gloves in that they provide the following characteristics:

- intended use
- size, configuration, packaging
- made of natural rubber latex
- tensile strength and thickness profiles

Summary of Testing:

<u>Test</u>	<u>Result</u>
Intracutaneous Reactivity	Glove does not elicit irritation following intradermal injection of extracts.
Kligman Maximization	Glove does not display sensitization potential to produce skin sensitization.
Ultimate Elongation & Tensile Strength	Glove meets or exceeds requirements for rubber examination gloves per ASTM D3578-95.
Barrier Defects	Glove meets or exceeds requirements per 21 CFR §800.20 and ASTM D3578-95, AQL=4.0.



XIV. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (con't) POWDER-FREE NON-STERILE LATEX EXAMINATION GLOVES WITH A PROTEIN LABEL CLAIM

Summary of Testing:

<u>Test</u>	<u>Result</u>
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.
	Gloves meet requirements for a low protein claim designation of 50 microgram or less of total water extractable protein per gram per glove using the ASTM Lowry test method (ASTM 5712-95).