

510(k) SUMMARY

DATE: February 17, 2012
OWNER: Northstar Healthcare Holdings
70 Sir John Rogerson's Quay
Dublin 2, Ireland

SEP 10 2012

OFFICIAL

CORRESPONDENT: Alex Nagy
Manager, Quality Systems and Regulatory Affairs
Cypress Medical Products LLC
1200 South Route 31
McHenry, IL 60050
Telephone: 815-385-0100
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DEVICE NAME: **Trade Name:** ETS Blue Powder Free Nitrile Patient Exam Glove
Common Name: Patient Examination Gloves
Classification: Patient Examination Gloves
Class: Class I
Product Code: LZA

PREDICATE DEVICE(S):

Predicate 510(k)	Device Name	Indication	Clearance Date	Company
K062764	Nitrile Powder Free Examination Gloves (White, Blue)	The patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	27 Feb 07	Kossan Latex Industries SDN BHN, Selangor Darul Ehsan, Malaysia

DEVICE DESCRIPTION: Powder free blue nitrile patient exam glove, meets all the requirements of ASTM standard D6319, except for sterility requirements.

STATEMENT OF INTENDED USE:

The nitrile examination glove is a disposable device intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

TECHNOLOGICAL CHARACTERISTICS:

The ETS Blue Powder Free Nitrile Patient Exam Glove is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use. Both gloves are made with nitrile using similar manufacturing processes.

Feature	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs (Blue, White) K062764 Predicate	ETS Blue Powder Free Nitrile Patient Exam Gloves Proposed
Intended Use	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Tested for Use with Chemotherapy Drugs.	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
Indications for Use Statement	The patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is not intended to be used as a chemical barrier.	The 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.
Description	Non-sterile, powder free, examination gloves made of nitrile and colored white. The textured gloves are provided in sizes extra small, small, medium, large and extra large. The smooth gloves are provided in sizes small, medium, large and extra large.	Same
Presentation	Non-sterile gloves are provided in dispenser boxes.	Same
Material	Nitrile	Same
Sterilization	Non-sterile	Same
Single Use	Yes	Same
Ambidextrous	Yes	Same
Dimensions	Meets ASTM D6319-10	Same
Tensile Strength	Meets ASTM D6319-10	Same
Ultimate Elongation	Meets ASTM D6319-10	
Freedom from Pinholes	Meets ASTM D5151-06 and ASTM D6319-10	Same
Residual Powder	Meets ASTM D6124-06	Same
Biocompatibility Tests	Passes Primary Skin Irritation in Rabbits	Same
	Passes Closed Patch Sensitization in Guinea Pigs	Same

**ASSESSMENT OF
NONCLINICAL DATA:**

Characteristic	Standard	Device Performance
Dimension	ASTM D6319	Meets
Physical Properties	ASTM D6319	Meets
Freedom from Pinholes	ASTM D6319 & ASTM D5151	Meets
Powder Residual	ASTM D6124	Meets Results generated values below 2mg of residual powder
Biocompatibility	Primary Skin Irritation in rabbits (ISO 10993-10)	Gloves are non-irritating
	Dermal Sensitization in the guinea pig (ISO 10993-10)	Gloves do not display any potential for sensitization

CONCLUSIONS:

The ETS Blue Powder Free Nitrile Patient Exam Gloves meet the requirements of established standards ASTM D6319-10, ASTM D6124-06, ASTM D5151-06, and ISO 10993-10.

Based on the comparison of intended use, design, materials and performance, the ETS Blue Powder Free Nitrile Patient Exam Gloves are substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Northstar Healthcare Holdings
C/O Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

SEP 10 2012

Re: K121947

Trade/Device Name: ETS Blue Powder Free Nitrile Patient Exam Gloves

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LZA

Dated: August 28, 2012

Received: August 28, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

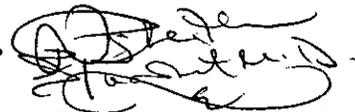
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

For 

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121947

Device Name: **ETS Blue Powder Free Nitrile Patient Exam Glove**

Indications for Use: The 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.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Clavin-Wells

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121947