FEB 0 8 2013

5.0 510(k) Summary K123488

Submitter / Manufacturer / 510(k) Owner:	Puyang Linshi Medical Supplies Co., Ltd.Industrial Park, Puyang County (East of Changsheng Road) Puyang City, 457100 Henan Province, China Telephone: 0086-393-333-1066 Fax: 0086-393-333-9566 Manufacturer Contact Person Mr. Frank Yanhai Lv Assistant of the President lvyanhai@linshichem.com
Application Correspondent:	Ms. Laura Weng Vice President, Operations lauraw@usalinshi.com Linshi Chemical America Co., Ltd. 17800 Castleton St. Suite# 328 City of Industry, CA 91748 Telephone: 626-581-3030 Fax: 626-581-3035
Date Prepared:	January 23, 2013
Trade Name:	Linshi Health Nitrile Disposable Exam Gloves, Powder-Free
Common Name:	Exam Gloves
Classification:	Class I Patient Examination Glove 21 CFR 880.6250
Product Code:	LZA
Predicate Device(s):	The subject device is equivalent to the following device: **K121947** ETS Blue Powder Free Nitrile Patient Examination Glove
Device Description:	Non-sterile, single-use, powder-free nitrile patient examination gloves (blue color), that meet requirements of ASTM D6139-10.
Intended Use:	A powder-free 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.

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Summary of Technological Characteristics

The powder-free blue nitrile examination glove is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use.

Feature	ETS Blue Powder Free Nitrile Exam Gloves K121947 Predicate Device	Linshi Health Nitrile Disposable Exam Gloves, Powder-Free Subject Device
Classification	Class I Patient Examination Glove	Same
Product Code	LZA	Same
Regulation	21 CFR 880.6250	Same
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.	A powder-free 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.
Description	Non-sterile, powder free, examination gloves made of nitrile and colored blue.	Same
Packaging	Non-sterile gloves are provided in dispenser boxes.	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	Same
Freedom from Pinholes	Meets ASTM D5151-06 and ASTM D6319-10	Same
Residual Powder	Meets ASTM D6124-06	Same
Biocompatibility	Passes Primary Skin Irritation in Rabbits	Same
	Passes Closed Patch Sensitization in Guinea Pigs	Same

Conclusion:

Puyang Linshi Health Co., Ltd. considers the Linshi Health Nitrile Disposable Exam Gloves, Powder-Free to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 8, 2013

Puyang Linshi Health Company, Limited
C/O Ms. Laura Weng
Vice President, Operations
Linshi Chemical America Company, Limited
17800 Castleton Street, Suite 328
CITY OF INDUSTRY CA 91748

Re: K123488
Trade/Device Name: Powder-Free Nitrile Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: LZA
Product Code: I
Dated: January 23, 2013
Received: January 24, 2013

Dear Ms. Weng:

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.

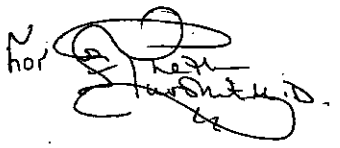
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4.0 Indications for Use Statement

Device Name:

Powder-Free Nitrile Examination Gloves, Blue Color

Indications for Use:

A powder-free 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.

Prescription Use _____ AND/OR Over-The-Counter Use __X_
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.02.07 16:55:51 -05'00'

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

510(k) Number: K123488