January 16, 2019

JiangSu DongXin Medical Technology Co., Ltd
℅ Chu Xiaoan
Official Correspondent
Beijing Easylink Co., Ltd
Rm. F302 Bldg., 41, Jing Cheng Ya Ju, Courtyard 6
of Southern Dou Ge Zhuang
Beijing, 100021 Cn

Re: K181106
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: November 27, 2018
Received: December 11, 2018

Dear Chu Xiaoan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181106

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue Color

Indications for Use *(Describe)*
Powder Free Nitrile Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K181106

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92

1.0 Submitter:

Submitter's name :	JiangSu DongXin Medical Technology Co.,Ltd
Submitter's address :	LongJin Road,The Economic Development Zone of SuCheng,SuQian City,JiangSu Province, 223800 China.
Name of contact person:	Deng Yujie
Date of preparation :	2019-01-14

Designated Submission Correspondent

Company's name	Beijing Easy-Link Company
Company 's address	Rm. F302 Bldg., 41, Jing Cheng Ya Ju, Courtyard 6 of Southern Dou Ge Zhuang, Chaoyang District, Beijing 100121, P.R. China
Contact person	Chu Xiaoan

2.0 Name of the Device

Proprietary/Trade name:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Common Name:	Patient Examination gloves
Classification Name:	Non-powdered Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Product Code:	LZA

3.0 Predicate device

Device Name:	Powder Free Nitrile Patient Examination Glove, Blue Color
Company name:	Tangshan Zhonghong Pulin Plastic Co., Ltd.
510(K) Number:	K120970

4.0 Device Description:

The proposed device is Powder Free Nitrile Examination Gloves. The proposed device is blue. The proposed device is non-sterile.

5.0 Indications for Use Statement:

Powder Free Nitrile Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Technological Characteristic Comparison Table:

Features & Description	Predicate Device (K120970)	Subject Device (K181106)	Comparison
Product name	Powder Free Nitrile Patient Examination Glove, Blue Color	Powder Free Nitrile Patient Examination Gloves, Blue Color	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	same
Product Code	LZA	LZA	same
Color	Blue	Blue	same
Size	Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	same
Indications for Use	Powder Free Nitrile Patient Examination Glove, Blue Color 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.	Powder Free Nitrile Patient Examination Gloves, Blue Color 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.	same
Device Description and Specifications	Meets ASTM D6319-10	Meets ASTM D6319-10	same
Dimensions --Length ILS-2 AQL4.0	Meets ASTM D6319-10 ≥230mm min	232 mm min for all sizes	similar
Dimensions -- Width IL S-2 AQL4.0	Meets ASTM D6319-10		similar
	Small 70-90 mm	Small 76-90 mm	
	Medium 85-105mm	Medium 89-102 mm	
	Large 100-120mm	Large 108-119mm	
	X large 110-130 mm	X large 115-128 mm	
Dimensions --Thickness IL S-2 AQL4.0	Meets ASTM D6319-10 Finger 0.05mm min. Palm 0.05mm min.	Thickness (mm) min. Finger 0.08 Palm 0.08	similar

Physical Properties IL S-2 AQL4.0	Meets ASTM D D6319-10 Before aging/after aging Tensile Strength≥ 14MPa Before aging Elongation ≥500% After aging Elongation ≥400%	Aging	Before	After	similar
		Elongation (%)	550-600	450-570	
		Tensile Strength (MPa)	18-25	17-22	
Freedom from Pinholes Inspection Level I AQL2.5	Meets • 21 CFR 800.20 • ASTM D6319-10	1) Inspection Level I AQL2.5,and Accept/Reject criteria of 10/11 2) Water leakage test: 5 noncompliance is allowed.			similar
Residual Powder	Meets ASTM D 6124-06 (Reaffirmation 2011) below 2mg of residual powder	1) Checked on 5pcs sub-samples (N=5). 2) Result as following: Mean: 0.1mg/pcs			similar
Materials used to fabricate the devices	Nitrile	Nitrile			same
Single Patient Use	Single Patient Use	Single Patient Use			same
Biocompatibility	Under the conditions of this study, the test article was a non-irritant or non-sensitizer	Under the conditions of this study, the test article was a non-irritant or non-sensitizer			similar
		Under the conditions of this study, the test article was non-cytotoxicity to L-929 cells.			
Labeling for the legally marketed device to which substantial equivalence is claimed.	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile			same

7.0 Discussion of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device will meet acceptance crtiteria for each test. The test results demonstrated that the proposed device met the

acceptance criteria found in the following standards below:

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
ASTM D5151-06(Reapproved2015), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6319-10(Reapproved 2015), Standard Specification for Nitrile Examination Gloves for Medical Application.

8.0 Discussion of Clinical and Performance Testing

Clinical testing is not needed for this device.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.