June 6, 2022

St Future International Limited
℅ Bing Huang
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
ShenZhen, GuangDong 518100
China

Re: K213448
Trade/Device Name: Powder Free Nitrile Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 28, 2022
Received: May 5, 2022

Dear Bing Huang:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213448

Device Name
Powder Free Nitrile Gloves

Indications for Use *(Describe)*
The Powder Free Nitrile Gloves is intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.
This device is a disposable product, provided non-sterile.

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.

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510 (k) Summary

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

K213448

(1) Applicant information:

510(k) owner's name:	ST FUTURE INTERNATIONAL LIMITED
Address:	FLAT/RM 08 9/F CHEVALIER COMMERCIAL CENTRE 8 WANG HOT ROAD KOWLOON BAY HK
Contact person:	Ivan Tan
Phone number:	+86-13416165207
Email:	qa01@st-future.com
Date of summary prepared:	2022-6-2

(2) Proprietary name of the device

Trade name/model:	Powder Free Nitrile Gloves
Common name:	Polymer Patient Examination Glove
Regulation number:	21 CFR 880.6250
Product code:	LZA
Review panel:	General Hospital
Regulation class:	Class I

(3) Predicate device

	Predicate device
Sponsor	Onetexx Sdn Bhd
Device Name and Model	Blue Nitrile Powder Free Patient Examination Glove, Non Sterile
510(k) Number	K210366
Product Code	LZA
Regulation Number	21 CFR 880.6250
Regulation Class	Class I

(4) Description/ Design of device:

The Powder Free Nitrile Gloves are non-sterile disposable patient examination gloves. The gloves are blue and powder free. The Powder Free Nitrile Gloves come in four sizes: Small, Medium, Large, X Large.

The Powder Free Nitrile Gloves act as a barrier to prevent contamination between patient and

examiner. The device meets all requirements of ASTM D6319-19.

(5) Indications for use:

The Powder Free Nitrile Gloves is intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.
This device is a disposable product, provided non-sterile.

(6) Materials

Product name	Material of product	Color additives	Body contract category	Contact duration
Powder Free Nitrile Gloves	Nitrile	Blue	Surface and external communicating device	Less than 24 hours

(7) Technological Characteristic Comparison Table

Item	Subject device	Predicate device	Remark
Company	ST FUTURE INTERNATIONAL LIMITED	Onetexx Sdn Bhd	/
Trade name	Powder Free Nitrile Gloves	Blue Nitrile Powder Free Patient Examination Glove, Non Sterile	/
510 (k) number	K213448	K210366	/
Regulation number	21CFR 880.6250	21 CFR 880.6250	Same
Product code	LZA	LZA	Same
Size	S/ M/ L/ XL	Extra Small/ Small/ Medium/ Large/ Extra Large	Same
Class	I	I	Same
Indications for use/ Intended use	The Powder Free Nitrile Gloves is intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. This device is a disposable product, provided non-sterile.	A patient examination glove is a disposable device made of synthetic rubber latex intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Similar, only wording difference

Dimensions:					
S	Length		246mm	249mm	Different but within the ASTM D6319
	Width		86.4mm	87.0mm	
	Thickness	Finger	0.11mm	0.10mm	
		Palm	0.08mm	0.07mm	
M	Length		243mm	249mm	
	Width		96.9mm	98.0mm	
	Thickness	Finger	0.12mm	0.10mm	
		Palm	0.09mm	0.07mm	
L	Length		255mm	248mm	
	Width		106mm	107mm	
	Thickness	Finger	0.12mm	0.10mm	
		Palm	0.09mm	0.07mm	
XL	Length		251mm	250mm	
	Width		116mm	117mm	
	Thickness	Finger	0.12mm	0.10mm	
		Palm	0.08mm	0.07mm	
Physical Properties: <u>Before Aging</u> Tensile strength Ultimate elongation <u>After Aging</u> Tensile strength Ultimate elongation			 34.56MPa 556% 36.34MPa 485%	 32.35MPa 568% 36.10MPa 551%	Different but within the ASTM D6319
Freedom from Pinholes Holes			In accordance with ASTM D5151-19 Inspection level: G-1 AQL=2.5	In accordance with ASTM D5151-19 Inspection level: G-1 AQL=2.5	Same
Residual Powder			0.3mg/glove	0.24mg/glove	Different but within the ASTM D6124
Materials used to fabricate the devices			Nitrile	Nitrile	Same
Color			Blue	Blue	Same

Compare performance data supporting substantial equivalence	Meets ASTM D5151-19 ASTM D6319-19 ASTM D6124-06 (Reapproved 2017)	Meets ASTM D5151-19 ASTM D6319-19 ASTM D6124-06 (Reapproved 2017)	Same
Single Use	Single Use	Single Use	Same
Biocompatibility	Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. Complies with ISO 10993-10:2010.	The test material did not produce a skin sensitization effect in the guinea pigs. Complies with ISO 10993-10:2010.	Same
	The test result showed that the irritant response of the test article extract was categorized as negligible under the test condition. Complies with ISO 10993-10:2010.	The test material did not cause an irritant response. The Primary Irritant Response Category is deemed 'Negligible'. Complies with ISO 10993-10:2010.	Same
	According to ISO 10993-5: 2009, the test material demonstrated a cytotoxic effect under the condition of this study. Additional test i.e. Acute Systemic Toxicity was tested.	According to ISO 10993-5: 2009, the test material demonstrated a cytotoxic effect under the condition of this study. Additional test i.e. Acute Systemic Toxicity was tested.	Same
	Under the conditions of this study, there was no evidence of systemic toxicity from the extract. Complies with ISO 10993-11:2017	The test item did not induce any systemic toxicity. Complies with ISO 10993-11:2017	Same
Shelf-life	3 years	Not known	Different Note 1

Note 1: Although the shelf-life data of the predicate device are unknown, but the subject device has been validated to the shelf-life of 3 years, so the difference does not affect safety and effectiveness.

(8) Summary of Non-Clinical Testing:

Powder Free Nitrile Gloves are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	**Standard**				**Result**
Dimension	ASTM D6319-19				
	Small	Length		≥220mm	246mm
		Width		80±10mm	86.4mm
		Thickness	Finger	≥0.05mm	0.11mm
			Palm	≥0.05mm	0.08mm
	Medium	Length		≥230mm	243mm
		Width		95±10mm	96.9mm
		Thickness	Finger	≥0.05mm	0.12mm
			Palm	≥0.05mm	0.09mm
	Large	Length		≥230mm	255mm
		Width		110±10mm	106mm
		Thickness	Finger	≥0.05mm	0.12mm
			Palm	≥0.05mm	0.09mm
	X large	Length		≥230mm	251mm
		Width		120±10mm	116mm
		Thickness	Finger	≥0.05mm	0.12mm
			Palm	≥0.05mm	0.08mm
Physical Properties	ASTM D6319-19				
	Before aging	Tensile strength		≥14MPa	34.56MPa
		Ultimate elongation		≥500%	556%
	After aging	Tensile strength		≥14MPa	36.34MPa
		Ultimate elongation		≥400%	485%
Freedom from pinholes	ASTM D5151-19			Passed Standard Acceptance Criteria, AQL=2.5	Pass, no water leakage
Powder Residual	ASTM D6319-19 and ASTM D6124-06 (Reapproved 2017)			Meets < 2.0 mg/ glove	0.3mg/glove
Biocompatibility	In vitro cytotoxicity ISO 10993-5:2009			The test material demonstrated a cytotoxic effect under the condition of this study	Cytotoxic. Additional test i.e. Acute Systemic Toxicity was tested.

	Acute Systemic Toxicity of Powder Free Nitrile Gloves ISO 10993-11: 2017	Under the conditions of this study, there was no evidence of systemic toxicity from the extract. The test article extract met the requirements of the study.	Pass
	Skin Irritation ISO 10993-10: 2010	The test result showed that the response of the test article extract was categorized as negligible under the test condition.	Pass
	Skin sensitization in the guinea pig ISO 10993-10: 2010	Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig.	Pass
Shelf-life	ASTM D7160-16	The study are following the table 1 lists three conditions (0, 50 ℃ ,70 ℃) for accelerate aging testing.	Pass and met 3 years of shelf-life.

The Powder Free Nitrile Gloves meet requirements per ASTM D6319-19, per ASTM D 5151-19, per ASTM D6124-06 (Reapproved 2017), ISO 10993-11: 2017 and ISO 10993-10: 2010.

(9) Summary of Clinical Testing

Clinical performance testing was not needed for this device.

(10) Conclusion

Based on the nonclinical tests performed, the subject device, Powder Free Nitrile Gloves, are as safe, as effective, and perform as well as the legally marketed predicate device, K210366, Blue Nitrile Powder Free Patient Examination Glove, Non-Sterile.