February 22, 2021

Nathan Trading Co., Ltd
% Abdel Halim, PharmD, MSc, PhD, DABCC
President
Global Quality and Regulatory Services
10 Scenic Way
Monroe, New Jersey 08831

Re: K203191
Trade/Device Name: LYDUS Nitrile Examination Gloves, Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA

Dear Abdel Halim:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 12, 2021. Specifically, FDA is updating this SE Letter as an administrative correction to correct an incorrect contact name and an incorrect 510(k) number and contact name in the header.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ryan Ortega, OHT4: Office of Surgical and Infection Control Devices, 240-402-2303, Ryan.Ortega@fda.hhs.gov.

Sincerely,

Ryan Ortega -S

Ryan Ortega, PhD
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

February 12, 2021

Nathan Trading Co., Ltd
℅ Abdel B. Halim, PharmD, MSc, PhD, DABCC
Responsible Third-Party Official
Global Quality and Regulatory Services
10 Scenic Way
Monroe, NJ 08831

Re: K203191
Trade/Device Name: LYDUS Nitrile Examination Gloves, Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: January 26, 2021
Received: January 28, 2021

Dear Rafael Aguila:

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,

Ryan Ortega -S

For CAPT. Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203191

Device Name

LYDUS Nitrile Examination Gloves, Powder Free

Indications for Use *(Describe)*

LYDUS Nitrile Examination Gloves, Powder Free is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers 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.

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"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."

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510(K) Summary K203191

LYDUS NITRILE EXAMINATION GLOVES, POWDER FREE

Preparation Date: February 9, 2021

1. SUBMITTER

Company Name: Nathan Trading Co., Ltd.
Company Address: 58 Moo 12 Palan Sub-District, Nathan District, Ubon Ratchathani 34170 Thailand

Contact Person: Prof. Dr. Chansamone Saiyasak
Telephone Number: +66-81-878-9953
Email: csaiyasak@nathantrad.com

2. NAME OF THE DEVICE

Trade Name / Proprietary Name: LYDUS Nitrile Examination Gloves, Powder Free
Device Name: LYDUS Nitrile Examination Gloves, Powder Free
Device Classification Name: Patient Examination Gloves
Device Class: Class I
Device Classification Number: 21 CFR 880.6250
Product Code: LZA

3. IDENTIFICATION OF THE LEGALLY MARKETED DEVICE

Predicate Device: K192333
Device Name: Blue Nitrile Examination Gloves Powder Free
Device Classification Name: Patient Examination Gloves
Device Classification Number: 21 CFR 880.6250
Device Class: Class I
Product Code: LZA
Review Panel: General Hospital

4. DEVICE DESCRIPTION

The subject device in this 510(k) Notification is LYDUS Nitrile Examination Gloves, Powder Free. The subject device is a patient examination glove made from nitrile compound, blue color, powder free and non-sterile (Per 21 CFR 880.6250, Class I). The device meets the specifications in ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application*.

5. INTENDED USE OF THE DEVICE

LYDUS Nitrile Examination Gloves, Powder Free is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

6. TECHNOLOGICAL CHARACTERISTIC COMPARISON FOR THE PROPOSED AND PREDICATE DEVICES

CHARACTERISTICS	DEVICE PERFORMANCE		REMARKS
	PREDICATE	**SUBJECT**	
510(k) Number	K192333	K203191	-
Device Name	Blue Nitrile Examination Gloves Powder Free	Nitrile Examination Gloves, Powder Free	-
Product Code	LZA	LZA	Same
Intended Use	JR MEDIC Blue Nitrile Examination Gloves Powder Free is disposable devices intended for medical purpose that are worn on the examiner's hand or fingers to prevent contamination between patient and examiner. The device is for over the-counter use.	LYDUS Nitrile Examination Gloves, Powder Free is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.	Same
Materials of Use (ASTM D6910/D6910M-19)	Nitrile compound	Nitrile compound	Same
Color	Blue	Blue	Same
Texture	Finger Textured	Finger Textured	Same
Size (ASTM D6319-19)	Small, Medium, Large, Extra Large	Small, Medium, Large, Extra Large	Same
Sterilization	Non-sterile	Non-sterile	Same
Usage	Single usage	Single usage	Same
Dimensions (ASTM D6319-19)	Length Min. 230 min Width Min 95+/-10 mm (for medium size)	Length Min. 230 min Width Min 95+/-10 mm (for medium size)	Same
Physical Properties (ASTM D6319-19)	**Before Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	**Before Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	Same
Thickness (ASTM D6319-19)	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
Powder Free (ASTM D6319-19)	≤2 mg/glove	≤2 mg/glove	Same

Freedom from Holes (Water Tight -1000 ml) – ASTM D6319-19 (Cross Reference D5151)	Passed	Passed	Same
Biocompatibility - SKIN SENSITIZATION - ISO 10993-10: 2010 (E)	Under the conditions of study not an irritant	Under the conditions of study not an irritant	Same
Biocompatibility - SKIN IRRITATION - ISO 10993-10: 2010 (E)	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
Biocompatibility - *IN VITRO* CYTOTOXICITY - ISO 10993-5: 2009(E)	Under the conditions of the cytotoxicity study, additional acute systemic toxicity testing results showed no systemic toxicity concern.	Exhibit cytotoxic reactivity at 100% extract concentration (Grade 4 with neat extract). Non-cytotoxic reactivity at 50%, 25%, 12.5% and 6.25% extract concentration.	Similar
Biocompatibility - ACUTE SYSTEMIC TOXICITY - ISO 10993-11: 2017(E)	Under the conditions of the study no systemic toxicity	No systemic toxicity under the experimental conditions employed	Similar
Manufacturer(s)	JR Engineering & Medical Technologies (M) SDN.BHD., Malaysia	Nathan Trading Co., Ltd., Thailand	---------

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods. Both devices meet the ASTM standard D6319-19.

7. NON-CLINICAL TESTING SUMMARY

PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Dimensions Test	To determine the width, length, and thickness of the gloves	**Width:** 91 mm (Mean) (for medium size) **Length:** 241 mm (Mean)(for medium size) **Thickness:** *Finger* – 0.13 mm (Mean) *Palm* – 0.09 mm (Mean)	Passed
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Requirements Test	To determine the tensile strength and ultimate elongation before and after acceleration aging	**Before Acceleration Aging:** Tensile Strength (MPa): 34 (Mean) Ultimate Elongation (%): 601 (Mean) **After Acceleration Aging:** Tensile Strength (MPa): 34 (Mean) Ultimate Elongation (%): 571 (Mean)	Passed
ASTM D6319-19 (ASTM D5151-11) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Passed
ASMT D6319-19 (ASTM D6124-11) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	$\leq$ 2.0 mg/glove	0.80 mg/glove

BIO-COMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the potential of the material under test to produce skin irritation in rabbits	Under the condition of study not an irritant	Under the condition of study not an irritant

ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the skin sensitization potential of the material both in terms of induction and elicitation in guinea pigs.	Under the conditions of the study not a sensitizer.	Under the conditions of the study not a sensitizer.
ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method	Under the conditions of study non cytotoxic	Exhibit cytotoxic reactivity at 100% extract concentration (Grade 4 with neat extract). Non-cytotoxic reactivity at 50%, 25%, 12.5% and 6.25% extract concentration.
ISO 10993-11:2017 Biological evaluation of medical devices— Part 11: Tests for acute systemic toxicity	The test item was evaluated for acute systemic toxicity in Swiss Albino Mice	Under the conditions of the study no systemic toxicity	Under the conditions of the study no systemic toxicity

8. CLINICAL TESTING SUMMARY

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9. CONCLUSION

The conclusions drawn from the non-clinical test demonstrate that the subject device in 510(k) submission, the LYDUS Nitrile Examination Gloves, Powder Free is as safe, as effective, and performs as well as or better than the legally marketed predicate device K192333