December 11, 2021

Siam NTD Corporation Co., Ltd.
Taweesak Waideemaneetrakoon
Manufacturer Manager
Third Party Review Group
120/259 Moo1, Bueng Yitho Sub-district, Thanyaburi
Pathum Thani,
Thailand

Re: K212085
Trade/Device Name: Siam NTD+ Nitrile Powder-Free Examination gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 17, 2021
Received: November 19, 2021

Dear Taweesak Waideemaneetrakoon:

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,

For Clarence W. Murray, III, PhD
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)*

K212085

Device Name
Siam NTD+ NITRILE POWDER-FREE EXAMINATION GLOVES

Indications for Use *(Describe)*
Siam NTD+ NITRILE POWDER-FREE EXAMINATION GLOVES 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.

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.

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510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

Date Summary Prepared: November 23, 2021

1. Submitter

Company name :	Siam NTD Corporation Co., Ltd.
Company address :	120/259 Moo1, Bueng Yitho Sub-district, Thanyaburi District
	Pathum Thani Thailand 12130
	Telephone: +66863257731
Contact Person :	Mr. Taweesak Waideemaneetrakoon,
	Manufacturer Manager
	Phone number : +66899268831
	E-mil : taweesak8831@gmail.com

2. Name of the Device:

Proprietary Name:	Siam NTD^{+} NITRILE POWDER-FREE EXAMINATION GLOVES
Common Name:	Siam NTD^{+} NITRILE POWDER-FREE EXAMINATION GLOVES
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Regulatory Class:	I
Product Code: LZA	
Regulation Number:	21 CFR 880.6250
Review Panel:	General Hospital

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3. IDENTIFICATION OF THE LEGALLY MARKETED DEVICE

Predicate: K192333, JR MEDIC, JR Engineering & Medical Technologies (M) SDN.BHD.

Device Name: Blue Nitrile Examination Gloves Powder Free

Device Classification Name: Polymer Patient Examination Glove

Device Classification Number: 21 CFR 880.6250

Device Class: Class I

Product Code: LZA

Review Panel: General Hospital

4. DEVICE DESCRIPTION

Siam NTD^{+} NITRILE POWDER-FREE EXAMINATION GLOVES is a glove made from nitrile butadiene rubber Latex that covers the hand up to the wrist. It is cuffed and equally wearable on either hand, free from differentiation between the left hand and the right. It has 4 sizes, i.e. small, medium, large and extra large. All variations share the same blue color. The glove is non-sterile and is for single use only, to be discarded after each examination is performed. It acts as a barrier between the examiner and the subject being examined in order to prevent contamination between them.

5. INDICATIONS FOR USE.

Siam NTD^{+} NITRILE POWDER-FREE EXAMINATION GLOVES 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.

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6. TECHNOLOGICAL CHARACTERISTIC COMPARISON FOR THE PROPOSED AND PREDICATE DEVICES

CHARACTERISTICS	DEVICE PERFORMANCE		REMARKS
	PREDICATE	SUBJECT	
510(K) Numbers	K192333	K212085	
Device Name	JR MEDIC Blue Nitrile Examination Gloves Powder Free	Siam NTD+ NITRILE POWDER-FREE EXAMINATION GLOVES	
Product Code	LZA	LZA	Same
Intended Use	JR MEDIC Blue 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.	Siam NTD+ NITRILE POWDER-FREE EXAMINATION GLOVES 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
Material 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

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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 a sensitizer	Under the conditions of study not a sensitizer	Same
Biocompatibility-SKIN IRRITATION – ISO 10993-10:2010 (E)	Under the conditions of study not an irritant	Under the conditions of study not an irritant	Same

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Biocompatibility – IN VITRO CYTOTOXICITY – ISO 10993-5:2009(E)	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern.	Under the conditions of the study, concentration of extract, 100%, 66%, 44%, 30%, 20% was cytotoxic., 13%, 9%, 6% are not cytotoxic and therefore the device extracts were evaluated by ISO 10993-11 - Test for Acute Systemic Toxicity.	Same
Biocompatibility – ACUTE SYSTEMIC TOXICITY – ISO 10993-11:2017(E)	Under the conditions of the study the device extracts do not pose a systemic toxicity concern	Under the conditions of the study did not reveal any systemic toxicity.	Same
Manufacturer(s)	JR Engineering & Medical Technologies (M) SDN.BHD	TOP GLOVE MEDICAL (THAILAND) CO., LTD	

There are no significant differences between the three 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	To determine the width, length, and thickness of the gloves	**Width**: Small: 80±10 mm Medium: 95±10 mm Large: 110±10 mm	**Width**: Small: 84 mm Medium: 95 mm Large: 104 mm

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Application - Physical Dimensions Test		X-Large: 120±10 mm Length: Small: 220 mm Medium: 230mm Large: 230 mm X-Large: 230 mm Thickness: Finger: 0.05 mm min for all sizes Palm: 0.05 mm min for all sizes	X-Large: 114 mm **Length**: Small: 247 mm Medium: 248 mm Large: 247 mm X-Large: 248 mm **Thickness**: **Finger**: Small: 0.11 mm Medium: 0.10 mm Large: 0.10 mm X-Large: 0.10 mm **Palm**: Small: 0.07 mm Medium: 0.07 mm Large: 0.07 mm X-Large: 0.07 mm **Cuff**: Small: 0.06 mm Medium: 0.05 mm Large: 0.05 mm X-Large: 0.06 mm
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical	To determine the tensile strength and ultimate elongation before and after	**Before Aging**: Tensile Strength (MPa): 14 (Min) for all sizes Ultimate Elongation (%): 500 (Min) for all sizes	**Before Aging**: **Tensile Strength**: Small: 31.2 Mpa Medium: 31.3 Mpa Large: 28.9 Mpa

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Requirements Test	acceleration aging	**<u>After Acceleration Aging</u>**: Tensile Strength (MPa): 14 (Min) for all sizes Ultimate Elongation (%): 400 (Min) for all sizes	X-Large: 27.8 Mpa **Ultimate Elongation**: Small: 540% Medium: 575% Large: 580% X-Large: 561% **<u>After Acceleration Aging</u>**: **Tensile Strength**: Small: 14.6 Mpa Medium: 15.5 Mpa Large: 15.4 Mpa X-Large: 14.9 Mpa **Ultimate Elongation**: Small: 413% Medium: 424% Large: 446% X-Large: 442%
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	Gloves Passed AQL 1.5
ASMT D6319-19 (ASTM D6124-11) Standard Test Method for Residual Powder on	To determine the residual powder in the gloves	$\leq$ 2.0 mg/glove	Small: 0.48 mg/glove Medium: 0.35 mg/glove Large: 0.38 mg/glove X-Large: 0.18 mg/glove

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Medical Gloves			

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	Under the conditions of the study, concentration of extract, 100%, 66%, 44%, 30%, 20% was cytotoxic., 13%, 9%, 6% are not cytotoxic

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ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for acute systemic toxicity	To determine the acute systemic toxicity potential of the test item extracts (both inside and outer surface) in Swiss Albino Mice	Under the conditions of the study no systemic toxicity	Under the conditions of the study did not reveal any 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 Siam NTD+ NITRILE POWDER-FREE EXAMINATION GLOVES is as safe, as effective, and performs as well as the legally marketed predicate device K192333