



February 21, 2022

Thai Medical Glove Co., Ltd.
Noppadol Polbundit
Operation Director
363/2 Moo 8, Tambol Bangphra
Sriracha, Chonburi 20110
Thailand

Re: K213500

Trade/Device Name: TMG Nitrile Powder Free Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 14, 2021
Received: November 1, 2021

Dear Noppadol Polbundit:

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/pmnmn.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,

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

Indications for Use

510(k) Number (if known)

K213500

Device Name

TMG NITRILE POWDER FREE EXAMINATION GLOVE

Indications for Use (Describe)

TMG nitrile powder free examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand 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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K213500
510(k) SUMMARY
Nitrile Powder Free Examination Gloves

1.0 Appliance Information

Applicant: THAI MEDICAL GLOVE CO., LTD
Address: 363/2 Moo 8, Tambol Bangphra, Sriracha, Chonburi.
THAILAND 20110
Phone Number: +6638-198-102
Fax Number: N/A
Email: info@thaimedicalglove.co.th
Name of Contact Person: Noppadol Polbundit (Mr)
Designation: Operation Director
Contact Number: 66 96 445 3256
Contact Email: Noppadol.p@thaimedicalglove.co.th
Date 510(k) summary prepared: February 07, 2022

2.0 Identification of the subject device

Trade/Proprietary Name(s): TMG NITRILE POWDER FREE EXAMINATION GLOVE
Common Name: Nitrile Powder Free Examination Gloves
Classification Name: Patient Examination Gloves
Device Class: I
product code: LZA
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

3.0 Predicate Device

Device Name: Palm Care Blue Nitrile Examination Gloves Powder Free
510(k): K202384
Common Name: Patient Examination Gloves
Classification Name: Patient Examination Gloves
Device Classification: I
Product Code: LZA
Regulation Number: 21 CFR 880.6250



4.0 Description of the Device

TMG Nitrile Examination Gloves Powder Free are Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR880.6250). The gloves are made from acrylonitrile-butadiene copolymer dispersion. These gloves are blue in color and are powder free.

5.0 Indication for Use of the Device

TMG nitrile powder free examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

6.0 Summary of Technological Characteristics of the Device Compared to the Predicate Device

Characteristics	Standards	Device performance		Comparison
		Predicate	Current	
510(k) Number	-	K202384	K213500	----
Manufacturer(s)	-	Hi-Care Thai Gloves Co. Ltd	THAI MEDICAL GLOVE CO., LTD.	----
Name of device	-	Blue Nitrile Examination Gloves Powder free	Blue Nitrile Examination Gloves Powder free	----
Indication for Use	Medical Gloves Guidance Manual - Issued on January 22, 2008	Blue Nitrile Examination Gloves Powder-free is disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner	TMG nitrile powder free examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	Similar
Material	ASTM D6319-19	Nitrile (NBR)	Nitrile (NBR)	Same
Color	-	Blue	Blue	Same
Texture	-	Textured Fingers	Textured Fingers	Same
Size	ASTM D6319-19	Extra Small Small Medium Large Extra Large	Small Medium Large Extra Large	Different



Characteristics	Standards	Device performance		Comparison
		Predicate	Current	
Single Use	Medical Gloves Guidance Manual - Issued on January 22, 2008 -Labeling	Single use	Single use	Same
Dimension	ASTM D6319-19	Meet ASTM D6319-19 Length 230 mm min. Width 95 ± 10 mm min (for Medium size)	Meet ASTM D6319-19 Length 230 mm min. Width 95 ± 10 mm min (for Medium size)	Same
Thickness	ASTM D6319-19	Meet ASTM D6319-19 Finger: 0.05 mm min Palm: 0.05 mm min	Meet ASTM D6319-19 Finger: 0.05 mm min Palm: 0.05 mm min	Same
Physical Properties	ASTM D6319-19	Meet ASTM D6319-19 <u>Before aging</u> Tensile Strength: 14 MPa min Ultimate Elongation: 500% min <u>After aging</u> Tensile Strength 14 MPa min Ultimate Elongation: 400% min	Meet ASTM D6319-19 <u>Before aging</u> Tensile Strength: 14 MPa min Ultimate Elongation: 500% min <u>After aging</u> Tensile Strength 14 MPa min Ultimate Elongation: 400% min	Same
Watertight test (1000 ml)	ASTM D5151-19	Pass AQL 1.5	Pass AQL 1.5	Similar
Powder Residue	ASTM D6124-06 (Reapproved 2017)	Meet ≤ 2.0 mg/glove	Meet ≤ 2.0 mg/glove	Similar



Characteristics	Standards	Device performance		Comparison
		Predicate	Current	
Biocompatibility	Primary Skin Irritation – ISO 10993-10 Third Edition 2010-08-01	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
	Dermal Sensitization – ISO 10993-10 Third Edition 2010-08-01	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
	In vitro cytotoxicity ISO10993-5 :2009(E)	Under the conditions of the study, noncytotoxic	Under the conditions of the study cytotoxic for undiluted, 1:2 and 1:4 dilutions but noncytotoxic for 1:8, 1:16 and 1:32 dilutions. Moreover, under the conditions of the study, non acute systemic toxic.	Different
	Acute Systemic Toxicity ISO10993-11:2017(E)	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	Under the conditions of the study, did not induce any systemic toxicity.	Same

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 standards.



7.0 Non-clinical testing summary

Performance Data

Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Dimension	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 230 mm for all sizes	Small: 243 mm Medium: 240 mm Large: 240 mm Extra Large: 240 mm	Pass
	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Small: 80 ± 10 mm Medium: 95 ± 10 mm Large: 110± 10 mm Extra Large: 120 ± 10 mm	Small: 85 mm Medium: 93 mm Large: 105 mm Extra Large: 115 mm	Pass
	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	Small: Palm 0.09 mm, Finger: 0.13 mm Medium: Palm: 0.06 mm, Finger: 0.08 mm Large: Palm 0.09 mm, Finger: 0.12 mm Extra Large: Palm 0.09 mm, Finger: 0.12 mm	Pass
Watertight test	ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	Sample size: 200 pcs Inspection level : G1 AQL 1.5 Acceptance Number 7 Rejection Number 8	The batch size for this sampling is 35,001-150,000. Hence, according to the single sampling plan G1, the sample to be drawn is under code L equivalent to 200 pcs with accept 7 and reject 8 to be accept under AQL 1.5... Small: 0 (Zero) Medium: 0 (Zero) Large:0 (Zero) Extra Large:0 (Zero).	Pass



Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Residual powder	ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 mg per glove or less	Sample size : 5 pcs Requirement: 2 mg per glove or less Result : Small:1.42 mg/glove Medium: 0.50 mg/glove Large: 1.34 mg/glove Extra Large:1.36 mg/glove	Pass
Physical Properties	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To Determine the physical properties- Tensile strength	Before Ageing Tensile Strength 14Mpa Minimal for all sizes After Ageing Tensile Strength 14Mpa Minimal for all sizes	Before Ageing Small: 18.37 MPa Medium: 30.62 MPa Large: 18.30 MPa Extra Large: 18.20 MPa After ageing: Small: 14.08 MPa Medium: 31.89 MPa Large: 14.00 MPa Extra Large: 14.00 MPa	Pass
		To Determine the physical properties- Ultimate Elongation	Before Ageing Ultimate Elongation 500% Min for all sizes After Ageing Ultimate Elongation 400% Min for all sizes	Before Ageing: Small: 612% Medium: 500 % Large:620% Extra Large:587% After ageing: Small:408% Medium: 499% Large:403% Extra Large:416%	Pass



8.0 Clinical Testing Summary

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

9.0 Conclusion

The conclusions drawn from the non-clinical test demonstrate that the subject device TMG Nitrile Powder Free Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device K202384.