October 13, 2021

Dr.Boo Company Limited
Darunee Varabuntoonvit
Marketing Director
662/1-4 Moo 3 Phanomsarakarm-Sattahip Rd,
Kaokansong
Sriracha, Chonburi 20110
Thailand

Re: K211374
Trade/Device Name: Proclean - 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: July 30, 2021
Received: September 7, 2021

Dear Darunee Varabuntoonvit:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211374

Device Name
PRO CLEAN - NITRILE POWDER FREE EXAMINATION GLOVES

Indications for Use *(Describe)*
A powder-free patient examination glove 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
Nitrile Powder Free Examination Gloves

1.0 Appliance Information

Applicant:	Dr.Boo Company Limited
Address:	662/1-4 Moo 3 Phanomsarakarm-Sattahip Rd, Kaokansong, Sriracha. Chonburi, 20110 Thailand
Phone Number:	+66 86 341 9085
Fax Number:	+66 38 290 245
Email:	marketing@drboo.co.th
Name of Contact Person:	Ms. Darunee Varabuntoonvit
Designation:	Marketing Director
Contact Number:	+66 81 617 2961
Contact Email:	darunee@drboo.co.th
Date 510(k) summary prepared:	July 30, 2021

2.0 Identification of the subject device

Trade/Proprietary Name(s):	PROCLEAN - NITRILE POWDER FREE EXAMINATION GLOVES
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

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4.0 Description of the Device

Blue 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

A powder-free patient examination glove 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.

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	New 510(k) submission	----
Manufacturer(s)	-	Hi-Care Thai Gloves Co. Ltd	Dr. Boo Company Limited	----
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 won on the examiner's hand to prevent contamination between patient and examiner	A powder-free patient 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	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	Extra Small Small Medium Large Extra Large	Same

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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 **Before aging** Tensile Strength: 14 MPa min Ultimate Elongation: 500% min **After aging** Tensile Strength 14 MPa min Ultimate Elongation: 400% min	Meet ASTM D6319-19 **Before aging** Tensile Strength: 14 MPa min Ultimate Elongation: 500% min **After aging** 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

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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, non-cytotoxic	Same
	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.

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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	Extra Small: 230 mm Small: 230 mm Medium: 240 mm Large: 236 mm Extra Large: 236 mm	Pass
	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Extra Small: 70 ± 10 mm Small: 80 ± 10 mm Medium: 95 ± 10 mm Large: 110± 10 mm Extra Large: 120 ± 10 mm	Extra Small: 68mm Small: 79 mm Medium: 96 mm Large: 110 mm Extra Large: 120 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	Extra Small: Palm 0.11 mm, Finger: 0.11 mm Small: Palm 0.09 mm, Finger: 0.10 mm Medium: Palm: 0.08 mm, Finger: 0.08 mm Large: Palm 0.10 mm, Finger: 0.11 mm Extra Large: Palm 0.10 mm, Finger: 0.11 mm	Pass

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Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
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 : GI 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 GI, 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... Extra Small: : 0 (Zero) Small: 0 (Zero) Medium: 0 (Zero) Large:0 (Zero) Extra Large:0 (Zero).	Pass
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 : Extra Small: 1.35 mg/glove Small:1.35 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** Extra Small: 18.08 MPa Small: 18.37 MPa Medium: 35.52 MPa Large: 18.30 MPa Extra Large: 18.20 MPa **After Ageing**: Extra Small: 14.01 MPa Small: 14.08 MPa Medium: 34.50 MPa Large: 14.00 MPa Extra Large: 14.00 MPa	Pass

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Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Physical Properties	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	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**: Extra Small: 611 % Small: 612% Medium: 601 % Large:620% Extra Large:587% **After Ageing**: Extra Small: 412 % Small:408% Medium: 529% 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 Nitrile Powder Free Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device K202384.