December 10, 2021

Thai Rubber Industry Company Limited
% Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE 114,
Aurora, Illinois 60504

Re: K212850
Trade/Device Name: ComfortPro Blue 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
Dated: August 13, 2021
Received: September 7, 2021

Dear Manoj Zacharias:

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,

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)*
K212850

Device Name
ComfortPro Blue Nitrile Examination Gloves Powder free

Indications for Use *(Describe)*

ComfortPro Blue Nitrile Examination Gloves Powder free is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K212850
510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

A. APPLICANT INFORMATION

510(K) Owner's Name	THAI RUBBER INDUSTRY COMPANY LIMITED
Address	738 MOO 5, MANAM KOO , PLUAKDAENG RAYONG 21140 THAILAND
Phone	+66-098-2520209
Fax	-
E-mail	vanida@thairubberindustry.com
Contact Person	Ms. Supawadee Phoungthong
Designation	Managing Director
Contact Number	+66-098-2520209
Contact Email	vanida@thairubberindustry.com
Date Submitted	December 9, 2021

B. DEVICE IDENTIFICATION

Name of the device	ComfortPro Blue Nitrile Examination Gloves Powder Free
Product proprietary or trade name	ComfortPro
Common or usual name	Nitrile Examination Gloves
Classification name	Polymer Patient Examination Glove
Device Classification	Class-1
Product Code	LZA
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Hi-Care Thai Gloves Co. Ltd.
510(k) Number	K202384
Regulatory Class	Class 1
Product code	LZA

D. DESCRIPTION OF THE DEVICE:

ComfortPro Blue Nitrile Examination Gloves Powder Free is Class I patient examination gloves bearing the product code LZA (21CFR880.6250). The gloves are made from Nitrile (NBR)100%. These gloves are blue in color, non-sterile, ambidextrous, powder free and single use only. Blue Nitrile Examination Gloves Powder Free are available in sizes X-small, Small, Medium, Large and X Large.

E. INDICATION FOR USE OF THE DEVICE:

ComfortPro Blue Nitrile Examination Gloves Powder Free is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE	SUBJECT	
510(K) Number	--	**K202384**	**K212850**	----
Name of device	--	Palm Care Blue Nitrile Examination Gloves Powder free	ComfortPro Blue Nitrile Examination Gloves Powder Free	----
Dimensions- Length	ASTMD 6319-19	Length Min 230 mm	Length > 230 mm **Size** / **Average** X-Small 250 Small 241 Medium 245 Large 242 X- Large 242	Similar
Dimensions- Width	ASTMD 6319-19	Width Min 95+/-10mm (for medium size)	Width Min 95+/-10mm (for medium size) **Size** / **Average** X-Small 80 Small 82 Medium 93 Large 103 X- Large 110	Similar
Physical Properties- Tensile Strength	ASTMD 6319-19	**Before Ageing** Tensile Strength min 14 Mpa **After Ageing** Tensile Strength min 14 Mpa	**Before Ageing** Tensile Strength > 14 Mpa **Size** / **Average** X-Small 27.2 Small 23.2 Medium 24 Large 26.2 X- Large 27.4 **After Ageing** Tensile Strength > 14 Mpa **Size** / **Average** X-Small 24.2 Small 23.8 Medium 27.6 Large 27.6 X- Large 27.9	Similar
Physical Properties- Ultimate Elongation	ASTMD 6319-19	**Before Ageing** Ultimate Elongation > 500%	**Before Ageing** Ultimate Elongation > 500% X-Small 620 Small 590 Medium 570 Large 570 X- Large 550	Similar

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

<table>
<tr><th>CHARACTERSTICS</th><th>STANDARDS</th><th colspan="2">DEVICE PERFORMANCE</th><th>REMARKS</th></tr>
<tr><td></td><td></td><td>PREDICATE</td><td>SUBJECT</td><td></td></tr>
<tr><td></td><td>ASTMD 6319-19</td><td><u>After Ageing</u>
Ultimate Elongation >400%</td><td><u>After Ageing</u>
Ultimate Elongation > 400%
X-Small: 600
Small: 560
Medium: 540
Large: 540
X- Large: 550</td><td>Similar</td></tr>
<tr><td>Thickness</td><td>ASTMD 6319-19</td><td>Palm min 0.05 mm
Finger min 0.05 mm</td><td>Palm > 0.05 mm Finger > 0.05 mm
Size | Palm (Actual value) mm | Finger (Actual value) mm
X-Small | 0.101 | 0.121
Small | 0.081 | 0.097
Medium | 0.091 | 0.108
Large | 0.092 | 0.108
X- Large | 0.091 | 0.111</td><td>Similar</td></tr>
<tr><td>Powder Residue</td><td>ASTMD 6319-19</td><td>≤2 mg/glove</td><td>≤2 mg/glove
Actual value :0.49 mg/glove</td><td>Similar</td></tr>
<tr><td rowspan="4">Biocompatibility</td><td>Primary Skin Irritation- ISO 10993-10:2010(E)</td><td>Under the condition of study not an irritant</td><td>Under the condition of study not an irritant</td><td>Same</td></tr>
<tr><td>Dermal Sensitization- ISO 10993-10:2010(E)</td><td>Under the conditions of the study not a sensitizer</td><td>Under the conditions of the study not a sensitizer</td><td>Same</td></tr>
<tr><td>In vitro cytotoxicity ISO10993-5 2009(E)</td><td>Under the conditions of the study, noncytotoxic</td><td>Under the conditions of the study cytotoxic for 100% test item extract and non-cytotoxic at 50%, 25%, 12.5% and 6.25% test item extracts. Moreover, under the conditions of the study, non acute systemic toxic.</td><td>Similar</td></tr>
<tr><td>Acute Systemic Toxicity Test ISO 10993-11:2017(E)</td><td>Under the conditions of study, the device extracts do not pose a systemic toxicity concern.</td><td>Under the condition of study, the device extracts did not reveal any systemic toxicity.</td><td>Same</td></tr>
<tr><td>Water Tight (1000 ml)</td><td>ASTM D 5151-19 AQL 2.5</td><td>Passes</td><td>Passes</td><td>Similar</td></tr>
<tr><td>Indication for Use</td><td>--</td><td>Blue Nitrile Examination Gloves Powder Free is disposable devices intended for medical purpose that are worn on the examiner’s hand to prevent contaminatio between patient and examiner.</td><td>ComfortPro Blue Nitrile Examination Gloves Powder Free is disposable device intended for medical purpose that is worn on the examiner’s hand to prevent contamination between patient and examiner.</td><td>Similar</td></tr>
</table>

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE	SUBJECT	
Material	ASTMD 6319-19	Nitrile (NBR)	Nitrile (NBR)	Same
Color	--	Blue	Blue	Same
Size	ASTMD 6319-19	Extra Small, Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	--	Nonsterile	Nonsterile	Same
Powder/Powder free	--	Powder free	Powder free	Same
Label and Labeling	Meets FDA's label and labeling requirements	Meets FDA's label and labeling requirements	Meets FDA's label and labeling requirements	Same
Manufacturer(s)	-	Hi-Care Thai Gloves Co. Ltd. Thailand.	THAI RUBBER INDUSTRY CO., LTD..	------

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 D 6319-19.

G. COMPARISON BASED ON ASSESSMENT OF NON-CLINICAL PERFORMANCE DATA

BENCH TEST DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
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	X-Small: 250mm Small:- 241mm Medium: - 245 mm Large:- 242 mm X-Large- 242 mm
ASTM D6319-19 Standard Specification for nitrile examination gloves for medical Application.	To determine the width of the gloves	X-Small:-70+/-10 mm Small:-80+/-10mm Medium:-95+/-10 mm Large:-110+/-10 mm X Large:- 120+/-10 mm	X-Small:- 80 mm Small:- 82mm Medium:-93mm Large:- 103mm X-Large-110mm

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT		
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	**Size** X-Small Small Medium Large X Large	**Palm** 0.101 mm 0.081mm 0.091 mm 0.092mm 0.091 mm	**Finger** 0.121 mm 0.097mm 0.108mm 0.108mm 0.111mm
ASTM D6319-19 Standard Specification for nitrile examination gloves for medical Application.	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 14 Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all sizes	**Size** X-Small Small Medium Large X Large	**Before ageing** 27.2 Mpa 23.2 Mpa 24 Mpa 26.2 Mpa 27.4 Mpa	**After ageing** 24.2 Mpa 23.8 Mpa 27.6 Mpa 27.6 Mpa 27.9 Mpa
	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	**Size** X-Small Small Medium Large X Large	**Before ageing** 620% 590% 570% 570% 550%	**After ageing** 600% 560% 540% 540% 550%
ASTMD 5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 2.5		
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	≤2 Mg/Glove	0.49 mg/glove		

BIOCOMPATIBILITY DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ISO 10993-10:2010(E) Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. Test done for irritation.	To evaluate the test item, for skin irritation test in New Zealand White rabbits.	Under the condition of study not an irritant	Under the condition of study, not an irritant

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ISO 10993 10:2010(E) Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. Test done for skin sensitization	To evaluate the test item, for the Skin Sensitization in Guinea pigs by maximization test.	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer
ISO10993-5:2009(E) Biological evaluation of medical devices - part 5, tests for In vitro cytotoxicity.	To evaluate the test item, for its ability to induce cytotoxicity using L-929 mouse fibroblast cells by Elution Method.	Under the conditions of the study, non-cytotoxic	Under the conditions of the study cytotoxic for 100% test item extract and non-cytotoxic at 50%, 25%, 12.5% and 6.25% test item extracts. Moreover, under the conditions of the study, non acute systemic toxic.
ISO 10993-11:2017(E) Biological evaluation of medical devices - part 11, tests for systemic toxicity.	To evaluate the test item, for Acute Systemic Toxicity in Swiss Albino Mice.	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	Under the condition of study, the device extracts did not reveal any systemic toxicity.

The performance test data of the non-clinical tests demonstrates that the subject device meet the acceptance criteria and the specifications found in the standards and test methodology.

The performance test data of the non-clinical tests meet following standards:

ASTMD 6319-19 Standard Specification for Nitrile examination gloves for medical Application.

ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves

ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

ISO 10993-5:2009 (E) Biological evaluation of medical devices - part 5, tests for In vitro cytotoxicity.

ISO 10993-11:2017(E) biological evaluation of medical devices - part 11, tests for systemic toxicity.

H. COMPARISON BASED ON ASSESSMENT OF CLINICAL PERFORMANCE DATA

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

I. CONCLUSION

The conclusions drawn from the non-clinical tests demonstrate that the subject device in 510(K) submission, ComfortPro Blue Nitrile Examination Gloves Powder Free is as safe, as effective, and performs as well as or better than the legally marketed predicate device K202384.