December 7, 2021

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

Re: K212438
Trade/Device Name: Comfortpro
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: November 4, 2021
Received: November 4, 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)*
K212438

Device Name
Comfortpro

Indications for Use *(Describe)*
Comfortpro latex examination powder free gloves 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY
K212438
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	+66-81-6298773, +66-85-6000373
Fax	-
E-mail	chawalit@thairubberindustry.com
Contact Person	Mr. Chawalit Tiyadechachai
Designation	Owner and Managing Director
Contact Number	+66-81-6298773, +66-85-6000373
Contact Email	chawalit@thairubberindustry.com , Chawalit.tiya@gmail.com
Date Submitted	July 15, 2021

B. DEVICE IDENTIFICATION

Name of the device	COMFORTPRO
Product proprietary or trade name	COMFORTPRO
Common or usual name	Latex examination powder free gloves
Classification name	Latex Patient Examination Glove
Device Classification	Class-1
Product Code	LYY
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Hi-Care Thai Gloves Co. Ltd.
510(k) Number	K202377
Regulatory Class	Class 1
Product code	LYY

D. DESCRIPTION OF THE DEVICE:

COMFORTPRO Latex Examination Powder Free Gloves are manufactured to meet all the current specifications listed under the ASTM Specification D3578-19, Standard Specification for Rubber Examination Gloves. They are made from Natural Rubber Latex. These gloves are Natural in color (No color added) and are powder free.

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

E. INDICATIONS FOR USE OF THE DEVICE:

COMFORTPRO latex examination powder free gloves is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
		PREDICATE	CURRENT	
510(k) Number	--	**K202377**	**K212438**	
Name of device	-- -	Palm Care Latex Examination Powder Free Gloves	ComfortPro latex Examination Powder Free Gloves	---
Dimensions- Length	ASTMD3578-19	Length > 230 mm	Length > 230 mm Size: Average X-Small: 245 mm Small: 238 mm Medium: 233 mm Large: 240 mm	Similar
Dimensions- Width	ASTMD3578-19	Width Min 95+/- 10 mm (for medium size)	Width Min 95+/-10 mm (for medium size) Size: Average X-Small: 77 mm Small: 81 mm Medium: 93 mm Large: 101 mm	Similar
Physical Properties- Tensile Strength	ASTMD3578-19	Before Ageing Tensile Strength > 18 Mpa After Ageing Tensile Strength > 14 Mpa	Before Ageing Tensile Strength > 18 Mpa Size: Actual value X-Small: 29.6 Small: 25 Medium: 26 Large: 24.9	Similar
			After Ageing Tensile Strength > 14 Mpa Size: Actual value X-Small: 25.5 Small: 24.1 Medium: 22.2 Large: 24.4	Similar

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

<table>
<tr><th>CHARACTERSTICS</th><th>STANDARDS</th><th colspan="3">DEVICE PERFORMANCE</th><th>Comparison</th></tr>
<tr><td></td><td></td><td>PREDICATE</td><td colspan="2">CURRENT</td><td></td></tr>
<tr><td>510(k) Number</td><td>--</td><td>K202377</td><td colspan="2">K212438</td><td></td></tr>
<tr><td>Physical Properties- Ultimate Elongation</td><td>ASTMD3578-19</td><td>Before Ageing
Ultimate Elongation > 650%
After Ageing
Ultimate Elongation >500%</td><td colspan="2"><u>Before Ageing</u>
Ultimate Elongation > 650%
Size: Actual value
X-Small: 810
Small: 760
Medium: 680
Large: 780
After Ageing
Ultimate Elongation > 500%
Size: Actual value
X-Small: 820
Small: 760
Medium: 650
Large: 760</td><td>Similar</td></tr>
<tr><td>Thickness</td><td>ASTMD3578-19</td><td>Palm > 0.08 mm Finger > 0.08 mm</td><td colspan="2">Palm > 0.08 mm
Finger > 0.08 mm
Size | Palm (Actual value) | Finger (Actual value)
X-Small | 0.102 mm. | 0.114 mm.
Small | 0.087 mm. | 0.109 mm.
Medium | 0.10 mm. | 0.122 mm.
Large | 0.108 mm. | 0.121 mm.</td><td>Similar</td></tr>
<tr><td>Powder Free Residue</td><td>ASTMD3578-19</td><td>≤2 mg/glove</td><td colspan="2">0.68 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 colspan="2">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 colspan="2">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, non-cytotoxic</td><td colspan="2">Under the conditions of the study, non-cytotoxic</td><td>Same</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 colspan="2">Under the conditions of study the device extracts do not pose a systemic toxicity concern</td><td>same</td></tr>
</table>

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON
		PREDICATE	CURRENT	
510(k) Number		**K202377**	**K212438**	
Water Tight (1000 ml)	ASTM D5151-19 AQL-2.5	Passes	Passes	Similar
Indication for Use		Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	ComfortPro latex examination powder free gloves is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Material	-	Natural Latex	Natural Latex	Identical
Color	-	Natural (No color is added)	Natural color (No color is added)	Similar
Size	ASTMD3578-19	X Small, Small, Medium, Large	X Small, Small, Medium, Large	Similar
Single Use	Medical Glove Guidance Manual-Labeling	Single Use	Single Use	Same
Sterile/nonsterile	-	Nonsterile	Nonsterile	Same
Powder/Powder free	-	Powder free	Powder free	Same
Label and Labeling	FDA Label requirements	Meets FDA's label and labeling requirements	Meets FDA's label and labeling requirements	Same
Manufacturer(s)	-	Hi-Care Thai Gloves Co. Ltd.	THAI RUBBER INDUSTRY COMPANY LIMITED	---

Both devices meet the ASTM standard D3578.

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

BENCH TEST DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT		
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the length of the gloves	Min 230 mm for all sizes	X-Small : 245 mm Small : 238 mm Medium : 233 mm Large : 240 mm		
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the width of the gloves	X-Small : 70+/-10 mm Small : 80+/-10 mm Medium : 95+/-10 mm Large : 111+/-10 mm	X-Small : 77 mm Small : 81 mm Medium : 93 mm Large : 101 mm		
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the thickness of the gloves	Palm 0.08 mm min for all sizes Finger 0.08 mm min for all sizes	**Size** X-Small Small Medium Large	**Palm** 0.102 mm 0.087 mm 0.10 mm 0.108 mm	**Finger** 0.114 mm 0.109 mm 0.122 mm 0.121 mm
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 18MPa Min for all sizes **After Ageing** Tensile Strength 14MPa Min for all sizes	**Size** X-Small Small Medium Large	**Before ageing** 29.6 MPa 25 MPa 26 MPa 24.9 MPa	**After ageing** 25.5 MPa 24.1 MPa 22.2 MPa 24.4 MPa
	To determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 650% Min for all sizes **After Ageing** Ultimate Elongation 500% Min for all sizes	**Size** X-Small Small Medium Large	**Before ageing** 810% 760% 680% 780%	**After ageing** 820% 760% 650% 760%

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ASTM D5151-19 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	Medium : 0.68 mg/glove
ASTM D5712-15 (Reapproved 2020) Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method	To determine the extractable protein in the gloves.	200 µg/ dm² Max	Medium : 187.1 µg/ dm²

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
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% (neat) test item extract. As a follow up, acute systemic toxicity testing was performed to demonstrate the extract did not present an acute systemic toxicity concern.
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 conditions of study the device extracts do not pose a systemic toxicity concern

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

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

ASTM D3578-19 Standard Specification for Rubber Examination Gloves

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

ASTM D5712-15 (Reapproved 2020) Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method

ISO 10993-10:2010 (E) 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 conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission ComfortPro Latex Examination Powder Free Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device **K202377**.