December 1, 2020

Hi-Care Thai Gloves Co. Ltd.
℅ Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE 114
Aurora, Illinois 60504

Re: K202377
Trade/Device Name: Latex Examination Powder Free Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: October 31, 2020
Received: November 3, 2020

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,

For: CAPT Elizabeth Claverie, M.S.
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)*
K202377

Device Name
Latex Examination Powder Free Gloves

Indications for Use *(Describe)*

Latex Examination Powder Free Gloves are 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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510K SUMMARY

K202377

As required by
21CFR§807.92(c)

A. APPLICANT INFORMATION

Applicant	Hi-Care Thai Gloves Co. Ltd.
Address	199Moo.11, T.Banpru, A.Hatyai, Songkhla 90250, Thailand.
Phone	+66-92 225 8472
Fax	+66-74-291044
E-mail	daniel@hicarethai.com
Contact Person	Mr. Daniel John
Designation	International Operations Manager,
Contact Number	+66-92 225 8472
Contact Email	daniel@hicarethai.com
Date Submitted	August 5th, 2020

B. DEVICE IDENTIFICATION

Name of the device	Latex Examination Powder Free Gloves
Proprietary or trade name	Palm Care Latex Examination Powder Free Gloves
Common or usual name	Latex Examination Powder Free Gloves
Classification name	Patient Examination Glove
Device Classification	Class I
Product Code	LYY
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate device	JR Medic Powder Free Latex Examination Gloves
Predicate 510(K)	K192329
Regulatory Class	Class I
Product code	LYY

D. DESCRIPTION OF THE DEVICE

Latex Examination Powder Free Gloves are manufactured to meet all the current specifications listed under the ASTM Specification D 3578-05 (Reapproved 2015), Standard Specification for Rubber Examination Gloves. They are made from Natural Rubber Latex. These gloves are natural in color (no color is added) and are powder free.

E. INDICATIONS FOR USE/INTENDED USE OF THE DEVICE:

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.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS BETWEEN PREDICATE AND SUBJECT DEVICES

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON
		PREDICATE	CURRENT		
510(k) Number	---	K192329	K202377		
Name of device	---	JR MEDIC Blue Latex Examination Powder Free Gloves	Latex Examination Powder Free Gloves		---
Dimensions- Length	ASTMD3578-05 (Reapproved 2015)	Length > 230 mm	Length > 230 mm		Similar
			Size	Average	
			X-Small	303	
			Small	304	
			Medium	304	
			Large	305	
Dimensions- Width	ASTMD3578-05 (Reapproved 2015)	Width Min 95+/-10 mm (for medium size)	Width Min 95+/-10 mm (for medium size)		Similar
			Size	Average	
			X-Small	75	
			Small	84	
			Medium	94	
			Large	105	
Physical Properties- Tensile Strength	ASTMD3578-05 (Reapproved 2015)	Before Ageing Tensile Strength > 18 Mpa After Ageing Tensile Strength > 14 Mpa	Before Ageing Tensile Strength > 18 Mpa		Similar
			Size	Actual value	
			X-Small	22.13	
			Small	22.20	
			Medium	22.25	
			Large	22.28	
			After Ageing Tensile Strength > 14 Mpa		Similar
			Size	Actual value	
			X-Small	18.57	
			Small	18.64	
			Medium	18.70	
			Large	18.74	

<table>
<tr><th>CHARACTERSTICS</th><th>STANDARDS</th><th colspan="2">DEVICE PERFORMANCE</th><th>COMPARISON</th></tr>
<tr><td></td><td></td><td>PREDICATE</td><td>CURRENT</td><td></td></tr>
<tr><td>510(K) Number</td><td></td><td>K192329</td><td>K202377</td><td></td></tr>
<tr><td>Physical Properties- Ultimate Elongation</td><td>ASTMD3578-05 (Reapproved 2015)</td><td>Before Ageing
Ultimate Elongation > 650%
After Ageing
Ultimate Elongation >500%</td><td><u>Before Ageing</u>
Ultimate Elongation > 650%
Size | Actual value
X-Small | 867
Small | 871
Medium | 874
Large | 877
After Ageing
Ultimate Elongation > 500%
Size | Actual value
X-Small | 845
Small | 848
Medium | 854
Large | 860</td><td>Similar</td></tr>
<tr><td>Thickness</td><td>ASTMD3578-05 (Reapproved 2015)</td><td>Palm > 0.08 mm
Finger > 0.08 mm</td><td>Palm > 0.08 mm
Finger > 0.08 mm
Size | Palm (Actual value) | Finger (Actual value)
X-Small | 0.16 | 0.21
Small | 0.16 | 0.21
Medium | 0.16 | 0.21
Large | 0.16 | 0.21</td><td>Similar</td></tr>
<tr><td>Powder Free Residue</td><td>ASTMDD 3578-10 (Reapproved2015)</td><td>≤2 mg/glove</td><td>≤2 mg/glove
Size | Residual powder content (mg/glove)
X-Small | 0.21
Small | 0.21
Medium | 0.22
Large | 0.22</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>Material mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151></td><td>Under the conditions of the study non pyrogenic</td><td colspan="2">Under the conditions of the study, non-pyrogenic</td><td>Same</td></tr>
</table>

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON
		PREDICATE	CURRENT	
510(K) Number		K192329	K202377	
Biocompatibility	Bacterial Endotoxin test USP 42<85>	No data available	<20EU/pair of gloves	-----
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	Under the condition of study, not systemic toxic	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	same
Water Tight (1000 ml)	ASTM D5151-06 (Reapproved 2015)	Passes AQL-1.5	Passes AQL-1.5	Same
Intended use		JR MEDIC Blue Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Same
Material	-	Natural Latex	Natural Latex	Identical
Color	-	Blue	Natural (No color is added)	different
Texture	-	Finger Texture	Finger texture	Identical
Size	ASTMD 3578-5 (Reapproved 2015)	Small, Medium, Large & X Large	X Small, Small, Medium, Large,	Similar
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Non sterile	Non sterile	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)	-	JR Engineering & Medical Technologies (M) SDN.BHD. Malaysia.	Hi-Care Thai Gloves Co. Ltd.	---

G. SUMMARY OF NON-CLINICAL PERFORMANCEDATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the length of the gloves	Min 230 mm for all sizes	X-Small:-303 mm Small:-304mm Medium:-304mm Large:-305mm
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the width of the gloves	X-Small:-70+/-10 mm Small:-80+/-10mm Medium:-95+/-10 mm Large:-111+/-10 mm	X-Small:-75 mm Small:-84 mm Medium:-94mm Large:-105mm

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT		
ASTM D3578-05 (Reapproved 2015) Standard Specification For Rubber Examination Gloves	To determine the thickness of the gloves	Palm 0.08 mm min Finger 0.08 mm min for all sizes	Size X-Small Small Medium Large	Palm 0.16mm 0.16mm 0.16mm 0.16mm	Finger 0.21mm 0.21mm 0.21mm 0.21mm
ASTM D3578-05 (Reapproved 2015) 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 22.13Mpa 22.20Mpa 22.25Mpa 22.28Mpa	After ageing 18.57Mpa 18.64Mpa 18.70Mpa 18.74Mpa
	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 867% 871% 874% 877%	After ageing 845% 848% 854% 860%
	To Determine the physical properties-stress at 500% Elongation	Before Ageing 5.5 Mpa Max for all sizes	Size X-Small Small Medium Large	Before ageing 5.1 Mpa 5.1Mpa 5.2 Mpa 5.2Mpa	NA
ASTM D5151-06 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 1.5		
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 Max	Size X-Small Small Medium Large	Residual Powder Content 0.21 mg/glove 0.21 mg/glove 0.22 mg/glove 0.22 mg/glove	
ASTM D 5712-95 (Re approved 2010) Standard Test Method for the Analysis of Protein in Natural Rubber	To determine the extractable protein in the gloves.	200 µg/ dm^2 Max for all sizes	Size X-Small Small Medium Large	Extractable Protein content 50 µg/ dm^2 50 µg/ dm^2 50 µg/ dm^2 50 µg/ dm^2	

H. SUMMARY OF CLINICAL PERFORMANCEDATA

Not applicable.

I. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission Latex Examination Powder Free Gloves (K202377) is as safe, as effective, and performs as well as or better than the legally marketed predicate device K192329.