August 25, 2022

Iconic medicare sdn bhd
% A.C. Thirumaran
Official Correspondent
Integrated Assessment Services Pvt Ltd
1495, Manasarovar, 16th Main road, Anna Nagar West
Chennai, Tamil Nadu 600040
India

Re: K221648
Trade/Device Name: Iconic Latex Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: May 20, 2022
Received: June 7, 2022

Dear A.C. Thirumaran:

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,

Bifeng Qian, M.D., Ph.D
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)*
K221648

Device Name
Iconic Latex Glove

Indications for Use *(Describe)*
This non-powdered patient examination glove is a disposable device intended for medical purposes 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

510(k) No: K221648

1.0 Submitter:

Mr. Tan Cho Chia
Managing Director
Company Name: Iconic Medicare Sdn Bhd.
Company Address: PMT 798, LINGKARAN CASSIA SELATAN, TAMAN PERINDUSTRIAN BATU KAWAN, 14110 BANDAR CASSIA, PULAU PINANG.
MALAYSIA
Email: cctan@iconic.com.my
Telephone: 60 4 504159
Date of Summary Prepared: 15th March 2022

2.0 Subject Device Identification:

Trade Name / Proprietary Name: Iconic Latex Glove
Device Common Name: Non-powder Patient Examination gloves.
Device Classification Name: Natural Rubber Latex Patient Examination gloves
Device Classification: 1
Regulation Number: 21 CFR 880.6250
Product Code: LYY

3.0 Official Correspondent

Mr. A.C. Thirumaran
Integrated Assessment Services Private Limited
No.1495, Manasarovar, 16th Main road,
Anna Nagar west, Chennai- 600040, India.
Telephone: 91-44-26162670
Email: iasfda16@gmail.com

4.0 Identification of the Legally Marketed Device:

Predicate Device: Careglove Global SDN BHD
510k Number: - K161833
Device Name: Latex Examination Gloves Powder Free
Classification Name: Natural Rubber Latex Patient Examination Gloves
Device Classification: 1
Regulation Number: 21 CFR 880.6250

5.0 Device Description

The subject device in this 510(k) Notification is Iconic Latex Glove - Powder Free Latex Examination Glove. The subject device is a patient examination glove made from Latex compound, Natural White color, powder free and non-sterile (Per 21 CFR 880.6250 - class I). The device meets the specifications in ASTM D3578-19 Standard specification for Rubber Examination Gloves. The available sizes of the subject devices are Small, Medium, Large, X-Large.

6.0 Indications for Use

Iconic Latex Glove. This non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

7.0 Technological characteristics Comparison for the proposed and predicate devices

The Iconic Latex Glove is a Powder Free Latex Examination Glove, Non-sterile, with the following summarized technological characteristics, in comparison to the Predicate device and specifications in ASTM D3578-19.

Characteristics	Acceptance Criteria	Subject device: Iconic Latex Glove (Small, Medium, Large, X-Large)	Predicate Device Latex Examination Gloves Powder Free Careglove Global SDN BHD	Comparison Analysis
510(k) Number	-	K221648	K161833	-
Product Code	LYY	LYY	LYY	same
Intended use	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. The device is for over-the-counter use.	This powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The device is for over-the- counter use.	A 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.	same
Material used	Latex - Natural Rubber	Latex - Natural Rubber	Latex - Natural Rubber	same
Color	N/A	Natural White	Natural White	same
Sterility	Sterile/Non-sterile	Non sterile	Non sterile	same
Single use	Single use	Single use	Single use	same
Dimensions	Overall Length (mm) Min 230mm	Meets ASTM D3578-19	Meets ASTM D3578-19	same
	Width (±10mm) Small - 80 Medium- 95 Large-110 X-large-120	Meets ASTM D3578- 19	Meets ASTM D3578- 19	

Characteristics	Acceptance Criteria	Subject device: Iconic Latex Glove (Small, Medium, Large, X-Large)	Predicate Device Latex Examination Gloves Powder Free Careglove Global SDN BHD	Comparison Analysis
	Thickness at Palm (mm) Min; 0.05 mm	Meets ASTM D3578- 19	0.06– 0.09mm	
	Thickness at Finger Tip (mm) Min 0.05 mm	Meets ASTM D3578- 19	0.07– 0.10mm	
Physical Properties	Before Aging Tensile Strength = 18 MPa, min. Ultimate Elongation = 650 % min Stress at 500 % Elongation (MPa) After Accelerated Aging Tensile Strength =14 MPa, min. Ultimate Elongation = 500 % min	Meets ASTM D3578- 19	Meets ASTM D3578- 19	same
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151- 19	Meets ASTM D5151- 19	same
Residual Powder	< 2.0 mg/pc	Meets ASTM D6124- 06	Meets ASTM D6124- 06	same
Bio-Compatibility	ISO 10993-23:2010 Biological evaluation of medical devices: Tests for irritation	Under the conditions of this study, the test article was a non- irritant.	N/A	same
	ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests For skin sensitization	Under the conditions of this study, the test article was a non- sensitizer.	N/A	same
	ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Complies with the requirement of this standard	N/A	Same

Characteristics	Acceptance Criteria	Subject device: Iconic Latex Glove (Small, Medium, Large, X-Large)	Predicate Device Latex Examination Gloves Powder Free Careglove Global SDN BHD	Comparison Analysis
	ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Not induce systemic toxicity	N/A	Same
Extractable Protein	Water Extractable Protein, Maximum 50 µg/dm^2 ASTM D 5712-15	Small = 10.3 µg/dm^2 Medium = 8.7 µg/dm^2 Large = 9.9 µg/dm^2 X Large = 8.8 µg/dm^2	< 50 µg/dm^2	Same

8.0 Summary of non-clinical testing results

Iconic Nitrile Glove was tested and found in conformance with the following standards:

ASTM D3578-19	Standard Specification for Rubber Examination Gloves for Medical Application
ASTM D5151-19	Standard Test Method for detection of Holes in Medical Gloves
ASTM D6124-06	Standard Test Method for Residual Powder on Medical Gloves
ASTM D5712 -15	Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method
ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation on medical device Part 10: Test for Skin Sensitization
ISO 10993-11:2017	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation

Test Methodology	Purpose	Acceptance Criteria	Average Results				Final Results
			SMALL	Medium	Large	X Large	
ASTM D3578-19	Sterility	-	Non sterile	Non sterile	Non sterile	Non sterile	-
	Freedom from hole - ASTM D5151-19	AQL 2.5	Pass	Pass	Pass	Pass	Pass
	Dimension - width, Length, Thickness	Overall Length (mm) Min 230mm.	230.8	240.5	237.5	236.8	Pass
		Width (±10mm) Small - 80 Medium - 95 Large -111 X-large - 120	83	96	108.4	118.7	Pass
		Thickness at Palm & fingertip Min: 0.08 mm					

Test Methodology	Purpose	Acceptance Criteria	Average Results				Final Results
			SMALL	Medium	Large	X Large	
		Palm	0.14	0.13	0.12	0.14	Pass
		Fingertip	0.10	0.10	0.09	0.14	Pass
	Physical properties before aging, after accelerated aging	a. Before Aging					
		Tensile Strength=18 MPa, min.	20.8	23.4	21.4	20.7	Pass
		Ultimate Elongation= 650% min	1018.7	878.9	1127.9	1097.6	Pass
		Stress at 500% Elongation	3.3	3.9	3.7	3.3	Pass
		b. After Accelerated Aging					
		Tensile Strength=14 MPa, min.	15.3	17.3	16.9	17.4	Pass
		Ultimate Elongation= 500 % min	856.4	890.8	1077.3	956.8	Pass
	Powder-free Residue exceeds maximum limit - ASTM D6124-06	< 2.0 mg per glove	0.12	0.26	0.38	0.18	Pass
	Extractable Protein content	50 µg/dm2	10.3	8.7	9.6	8.8	Pass
ISO 10993-5	Test for Invitro cytotoxicity	Cytotoxic Characteristics					Pass
ISO 10993-10	Test for irritation and Skin Sensitization	Non - Skin Sensitized					Pass
ISO 10993-11	Tests for systemic toxicity	Not induce systemic toxicity					Pass
ISO 10993-23	Tests for irritation	Non-Irritant					Pass

9.0 Summary of clinical Performance data

Not applicable - Clinical data was not used to assess performance of the subject device.

10.0 Conclusion

The Conclusion drawn from the Non-Clinical test demonstrates that the subject device- Iconic Latex Glove is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K161833.