March 22, 2022

Lienteh Technology Sdn Bhd
Irsyad Mazuki
Senior RA Executive
Lot 6483, Jalan Sungai Puloh KU 5, Kawasan Perindustrian
Sungai Puloh
Klang, Selangor 42100
Malaysia

Re: K213678
Trade/Device Name: Powder Free Blue Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: March 4, 2022
Received: March 14, 2022

Dear Irsyad Mazuki:

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)*

K213678

Device Name
Powder Free Blue Nitrile Examination Gloves

Indications for Use *(Describe)*
Powder Free Blue Nitrile Examination Gloves are disposable device intended for medical purposes that are 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.

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LIENTEH TECHNOLOGY SDNBHD

K213678

510k Summary

As required by 21 CFR 807.92

1) **Submission Information**:

Date	: 11th October 2021
Type of 510(k) Submission	: Traditional
Basis for 510(k) Submission	: New Device
Applicant	: Lienteh Technology Sdn Bhd Lot 6483 Jalan Sg Puloh, KU5 Kawasan Perindustrian, Lorong Sungai Puloh, 42100 Klang, Selangor.
Contact Person	: Mohd Irsyad (Regulatory Affairs cum Senior QA Engineer) Lot 6483 Jalan Sg Puloh, KU5 Kawasan Perindustrian, Lorong Sungai Puloh, 42100 Klang, Selangor.

E-mail: irsyadmazuki@lienteh.com

Tel: +6014-5157 058

1) **Device:**
Proprietary Name: Powder Free Blue Nitrile Examination Gloves
Classification Name: Examination Gloves
Regulation Number: 880.6250
Product code: LZA
Device Class: I
Review panel: General Hospital

2) **Device Description**

The nitrile rubber is watertight under normal conditions of use. Its tensile properties cause it to conform to the hand, allowing movements necessary for the medical properties. ASTM conforming tensile properties create a glove that is strong and flexible. The glove is manufactured in accordance with the requirements of ASTM D6319-19 and ASTM D5151-19. This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between patient and examiner.

3) **Identification of the Legally Marketed Devices**

Class 1 Nitrile Patient Examination Gloves LZA, powder free that meets all the requirements of ASTM standard D6319-19 and FDA water leak test.

4) **The Intended Use of Gloves**

A medical glove is worn on the examiner's hand to prevent contamination between patient and examiner.

Technological Characteristics:

Table 1: General Comparison

Technological characteristics Comparison to Predicate Device			
	Subject Device Lienteh Technology Sdn Bhd's Powder Free Blue Nitrile Examination Gloves	**Predicate Device** Mercator Medical (Thailand) LTD's mCare Powder Free Nitrile Blue Examination Gloves -	Comparison
510K Number	K213678	K172930	
Indications for Use	Powder Free Blue Nitrile Examination Gloves are disposable device intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.	The device is a disposable device intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Design Specification	Meet ASTM D6319-19	Meet ASTM D6319-19	Same
Performance Physical Properties	Meet ASTM D6319-19	Meet ASTM D6319-19	Same
Material of Composition	Synthetic Nitrile Rubber	Synthetic Nitrile Rubber	Same

Biocompatibility: Animal Irritation Test Rabbit	Under the condition of study, not an irritant	Under the condition of study, not an irritant	Same
Dermal Sensitization Test- Guinea Pig	Under the condition of study, not a sensitizer	Under the condition of study, not a sensitizer	Same
Acute Systemic Cytotoxicity	Under the condition of the study, no adverse biological reaction	Under the condition of the study, no adverse biological reaction	Same
Color	Synthetic gloves with embedded colorant-Blue	Synthetic gloves with embedded colorant-Blue	Same
Sterility	Non-Sterile	Non-Sterile	Same
Powder Free	Meets applicable definition for Powder free; ≤ 2mg per glove	Meets applicable definition for Powder free; ≤ 2mg per glove	Same
Labelling Information	Single Use indication, Powder free, device name, gloves size, quantity, Patient examination gloves, Non-sterile	Single Use indication, Powder free, device name, gloves size, quantity, Patient examination gloves, Non-sterile	Same
Physical Properties as per ASTM D6319-19	**Before Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 400%	**Before Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 400%	Same
Dimension as per ASTM D6319-19	Finger Thickness: 0.06 – 0.10 mm Length: min 230 mm	Finger Thickness: Min 0.05 mm Length: min 230 mm	Similar
Freedom from holes	AQL per CFR 21.800.20 Test as per ASTM D5151-19	AQL per CFR 21.800.20 Test as per ASTM D5151-19	Same
Residual Powder	Tested to ASTM D6124 and meets requirement	Tested to ASTM D6124 and meets requirement	Same

- The biocompatibility test consists of Animal Irritation Test, Guinea Pig Sensitization (Buehler), and Acute Systemic Toxicity test were conducted and test reports are attached. The gloves pass the Biocompatibility test criteria of not being Sensitizers or irritants under the conditions of the test and no adverse biological reaction observed during the period of the study.
- Conclusion

  We concluded that the Non sterile, Powder Free Blue Nitrile Examination Gloves meet:

  - ASTM D6319-19 standard for
    - Watertight test for pinholes.
    - Physical properties.
    - Dimensions.
    - Residual Powder.

6) Non-clinical test was performed on the proposed device:

The proposed device was tested and conformed to the following standards and requirements stated in guidance for industry passed and FDA staff - Premarket Notification [510(k)] Submission issued on March 5, 2004:

- Table 2: Performance Testing Performance data of gloves based on animal studies, biocompatibility studies i) Skin irritation in rabbits, Guinea pig sensitization (Buehler) and acute systemic cytotoxicity test were conducted on Lienteh Technology Sdn Bhd's final and finished Powder Free Blue Nitrile Examination Gloves.

Test	Performance Testing- Animal Studies- essential principles	Acceptance Criteria	Powder Free Blue Nitrile Examination Gloves Results
I. Guinea Pig Sensitization	This test was designed to determine if the test article is a potential sensitizer to guinea pigs when applied atopically.	No deviations were noted, observed nor require clarification.	No reaction was observed upon removal of the test material and there was no positive allergic reaction observed on the test of guinea pigs during the challenge phase. None of the

				guinea pigs was sensitized. Conclusion: meets conformance requirements
II.	Primary Dermal Irritation in Rabbits	This test was designed to identify substances which are primary irritants to rabbit skin	No deviations were noted, observe nor require clarification.	Each test was individually examined and scored at 24 ± 2, 48 ± 2 and 72 ± 2 hours for erythema and edema using the Draize skin scoring scale. Results obtained as Primary Irritation Index was 0. Conclusion: meets conformance requirements.
III.	Acute Systemic Cytotoxicity in Rats	This test was designed to identify any adverse biological reaction following administration of the extracts of the test item on the rats.	No adverse reaction was noted, observed nor require clarification.	For the 4 days observation done on the test subject by doing: 1) Cage- side observation- all animals survived and appeared healthy and active through out of 4 days. 2) Body weight- all animals gained body weight through

			out of the 4 days. 3) Pathology- At sacrifice times, gross necropsies showed no abnormalities for any of the animals. Conclusion: meets conformance requirements.
			Conclusion: meets conformance requirements.
ASTM D5151-19	Pinhole Test	Free from holes, AQL 1.5	Pass
ASTM D6319-19	Physical Properties	<u>Before Aging</u> Tensile Strength: Min 14 MPa Elongation: Min 500% <u>After Aging</u> Tensile Strength: Min 14 MPa Elongation: Min 400%	Pass
ASTM D6124-06	Powder Residue	2 mg/glove maximum	Pass

Performance data of gloves based on ASTM D6319-19 and FDA Watertight Test

Test	**ASTM D6319-19 Standard Requirement**	**Powder Free Blue Nitrile Examination Gloves**
1. Watertight (1000mL) in accordance with ASTM D5151-19	Single Sampling in accordance with ISO 2859 **G1: AQL 2.5**	Pass G1: AQL 2.5
2. Length (mm) Size S M L XL	 Min 220 Min 230 Min 230 Min 230	 240mm minimum for all sizes
3. Palm width (mm) Size S M L XL	 80 ± 10 95 ± 10 110 ± 10 120 ± 10	 84 – 86 95-96 108 – 109 114 - 115
4. Thickness (mm) Single Layer Finger Palm Cuff	 Min 0.05 Min 0.05 Min 0.05	 Min 0.06 Min 0.06 Min 0.05
5. Physical Properties in accordance with ASTM D412-16 6. **Before Aging** Tensile Strength (MPa) Ultimate Elongation (%) **After Aging** Tensile Strength (MPa) Ultimate Elongation (%)	 Min 14 Min 500 Min 14 Min 400	 17 – 23 540 – 607 21 – 27 480 - 565

7. Powder Content in accordance with ASTM D6124-06	Max 2.0 mg/ glove	Below 2.0 mg/ glove

- The performance data of the glove as shown above meet ASTM D6319-19 the standards powder requirement of residual content below 2.0 mg per glove.
- The performance data above shows that Powder Free Blue Nitrile Examination Gloves meet- ASTM D6319-19 requirement of dimensions and tolerances. Data of actual test report is attached.
- The performance data above shows that Lienteh Technology Sdn Bhd's Powder Free Blue Nitrile Examination Gloves meet- ASTM D6319-19 requirements of properties tested in accordance with ASTM D412-16. Data of actual test report is attached.

7) Discussion of Non-clinical and Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

a) ISO 10993-10:2010 – Biological evaluation of medical devices- Part 10: Tests for Irritation and Skin Sensitization.
b) ISO 10993-11- Biological Evaluation of Medical devices- Part 11: Tests for Systemic toxicity.
c) ASTM D6124-06 (Reapproved 2017), Standard test method for Residual powder on medical gloves.
d) ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
e) ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

8) Clinical Test Conclusion

No clinical study is included in this submission.

9) Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject device is safe, as effective, and perform as well as or better than the legally marketed predicated K172930.