December 11, 2021

BYD Auto Industry Company Limited
% Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza,
Shuixi Road, Huangpu District
Guangzhou, Guangdong
China

Re: K212840
Trade/Device Name: Nitrile Gloves (Model: NE01)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 30, 2021
Received: September 7, 2021

Dear Cassie Lee:

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)*
K212840

Device Name
Nitrile Gloves (Model: NE01)

Indications for Use *(Describe)*
A disposable device intended for medical purposes that is worn on the examiner's hand or fingers 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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510(k) Summary

This summary of 510(K) is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary prepared: August 30, 2021

2. Submitter's Information

Sponsor Name: BYD Auto Industry Company Limited

Address: No.3001, 3007, Hengping Road, Pingshan, Shenzhen, Guangdong

Establishment Registration Number: Applying

Post Code: 518119

Contact name: Jianling Liu

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Tel: +86-136 3299 4277

E-mail: Liu.jianling@byd.com

Manufacture Factory:

Company: Hengchang(Dongying) Medical Technology Co.,Ltd.

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Contact name: Jianling Liu

Tel: +86-136 3299 4277

E-mail: Liu.jianling@byd.com

Application Correspondent:

Contact Person: Ms. Cassie Lee

Company: Share Info (Guangzhou) Medical Consultant Ltd.

Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China

Tel: +86 20 8200 6973

Email: regulatory@share-info.com

3. Subject Device Information

Type of 510(k): Traditional

Common Name: Polymer Patient Examination Glove

Classification Name: Non-powdered patient examination glove

Trade Name: Nitrile Gloves

Model Name: NE01

Review Panel: General Hospital

Product Code: LZA

Regulation Number: 21 CFR 880.6250

Regulatory Class: Class I

4. Predicate Device Information

Sponsor: Nathan Trading Co., Ltd.

Common Name: Polymer Patient Examination Glove

Classification Name: Non-powdered patient examination glove

Trade Name: LYDUS Nitrile Examination Gloves, Powder Free

510(k) Number: K203191

Review Panel: General Hospital

Product Code: LZA

Regulation Number: 21 CFR 880.6250

Regulatory Class: Class I

5. Device Description

The proposed devices are powder-free nitrile examination gloves, provided as non-sterile and disposable devices. The proposed devices are mainly made from nitrile and there are four sizes, includes small (S), medium (M), large (L), X-large (XL) for optional. The gloves are provided with blue color, the colorant is NBR BLUE 7214 (which composed of Phthalocyanine blue (CAS No.147-14-8) and Propylene glycol (CAS No.57-55-6). The examination glove is smooth surface with textured fingertips and a rolled rim atthe cuff edge.

The examination gloves meet the specifications in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

6. Intended Use / Indications for Use

A disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

7. Technological Characteristic Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate Device	Result

Elements of Comparison	Subject Device	Predicate Device	Result
Company	BYD Auto Industry Company Limited	Nathan Trading Co., Ltd.	--
510 (k) Number	K212840	K203191	--
Trade Name	Nitrile Gloves	Nitrile Examination Gloves, Powder Free	--
Product Code	LZA	LZA	
Classification Name	Non-powdered patient examination glove	Non-powdered patient examination glove	Same
Classification	Class I	Class I	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Indications For Use	A disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.	LYDUS Nitrile Examination Gloves, Powder Free is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.	Same
Material of Use	Nitrile compound	Nitrile compound	Same
Color	Blue	Blue	Same
Texture	Finger Textured	Finger Textured	Same
Size (ASTM D6319-19)	Small, Medium, Large, Extra Large	Small, Medium, Large, Extra Large	Same
Sterilization	Non-sterile	Non-sterile	Same
Usage	Single usage	Single usage	Same
Dimensions (ASTM D6319-19)	**Length:** For S: ≥220mm For M/L/XL: ≥230mm **Width:** For S: 80±10mm For M: 95±10 mm For L: 110±10 mm For XL: 120±10 mm	Length Min: 230 min (for medium size) Width Min: 95±10 mm (for medium size)	Same Note 1
Physical Properties	**Before Aging:**	**Before Aging:**	Same

Elements of Comparison	Subject Device	Predicate Device	Result
(ASTM D6319-19)	Tensile Strength: ≥14Mpa Ultimate Elongation: ≥500% **After Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥400%	Tensile Strength: Min 14 Mpa Ultimate Elongation: Min 500% **After Aging:** Tensile Strength: Min 14Mpa Ultimate Elongation: Min 400%	
Thickness (ASTM D6319-19)	Palm: ≥0.05mm Finger: ≥0.05mm	Palm min. 0.05 mm Finger min. 0.05 mm	Same
Powder Free (ASTM D6319-19)	≤2 mg/glove	≤2 mg/glove	Same
Freedom from Holes (Water Tight -1000 ml)-ASTM D6319-19 (Cross Reference D5151)	Passed	Passed	Same
Biocompatibility - Skin Sensitization (ISO 10993-10:2010)	Under the conditions of the study not a sensitization	Under the conditions of the study not a sensitizer	Same
Biocompatibility - Skin Irritation (ISO 10993-10:2010)	Under the conditions of study not an irritation	Under the conditions of study not an irritant	Same
Biocompatibility - Acute Systemic Toxicity (ISO 10993-11: 2017)	Under the conditions of the study no systemic toxicity	No systemic toxicity under the experimental conditions employed	Same

Comparison in Detail(s):

Note 1:

Although the “Dimensions” of subject device is a little difference with predicate devices, but they all met the requirements of the standard ASTM D6319-19..

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary:

Test Method	Test Purpose	Acceptance	Test Results	Conclus

		Criteria		ion
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Dimensions Test	To determine the width, length, and thickness of the gloves	**Width:** For M: 95±10mm For L: 110±10mm For XL: 120±10mm **Length:** For M: ≥230mm	For M: 93~96mm For L: 104-107mm For XL: 112~116mm For M: 236~239mm	Passed
		For L: ≥230mm For XL: ≥230mm	For L: 236~239mm For XL: 255~258mm	
		Thickness: Finger: ≥0.05mm Palm: ≥0.05mm	For M: Finger: 0.06~0.09mm Palm: 0.06~0.08mm For L: Finger: 0.06~0.08mm Palm: 0.06~0.08mm For XL: Finger: 0.08~0.10mm Palm: 0.06~0.09mm	
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Dimensions Test	To determine the tensile strength and ultimate elongation before and after acceleration aging	**Before Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥500% **After Aging:** Tensile Strength: ≥14Mpa Ultimate	**Before Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥500% **After Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation:	Passed

		Elongation: ≥400%	≥400%	
ASTM D6319-19 (ASTM D5151-11) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Pass at AQL 2.5	Passed
ASMT D6319-19 (ASTM D6124-11) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	< 2.0 mg/glove	For M: Pass at 0.46 mg/glove For L: Pass at 0.52 mg/glove For XL: Pass at 0.14 mg/glove	Passed

2) Biocompatibility Testing Summary:

Test Method	Test Purpose	Acceptance Criteria	Test Results	Conclusion
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin irritation and skin sensitization	To evaluate the potential intracutaneous reactivity caused by intracutaneously inject the extract to rabbits	Under the conditions of study not an irritation	Under the conditions of the study not a sensitization	Passed
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin irritation and skin sensitization	To determine the skin sensitization potential in guinea pigs.	Under the conditions of the study not a sensitization	Under the conditions of study not an irritation	Passed
ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for acute systemic toxicity	The test item was evaluated for acute systemic toxicity in ICR mouse	Under the conditions of the study no systemic toxicity	Under the conditions of the study no systemic toxicity	Passed

8.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

9. Final Conclusion：

The conclusions drawn from the nonclinical test demonstrate that the subject device is a safe, as effective, and perform as well or better than the legally marketed predicated K203191.