March 4, 2022
Dongguan Grinvald Technology Co., Ltd.
% Aristotle Nafpliotis
Regulatory Affairs Consultant/Engineer
mdi Consultants, Inc.
55 Northern Blvd
Great Neck, New York 11021

Re: K211808
Trade/Device Name: Medcare Powder-Free Blue Nitrile Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: January 31, 2022
Received: February 1, 2022

Dear Aristotle Nafpliotis:

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 Clarence W. Murray, III, 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)*
K211808

Device Name
Medcare Powder-Free Blue Nitrile Patient Examination Gloves

Indications for Use *(Describe)*
The powder free patient examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner. The device is for over the counter use.

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

The assigned 5l0(k) number is: K211808.

1. Submitter's Identification:

Date Summary Prepared: 4 March 2022

Dongguan Grinvald Technology Co.,Ltd.
401, Building3 No.4 of Guangming New Village 2 Road, Dongcheng ,
Dongguan City, Guangdong, China 523000

Contact: Dr. Anna Roxana Grinvald
Email : anna@gts-hk.net
Phone number 86 0769 23326470
Mobile phone no. 86 136 2261 7084

2. Name of the Device: Medcare Powder-Free Blue Nitrile Patient Examination Gloves

Model #: MD0120

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-powdered patient examination glove

Regulatory Class: Class 1

Product Code: LZA

3. Information for the 510(k) Cleared Device (Predicate Device):

510(K) Number: K200326

Trade Name: Powder Free Nitrile Examination Glove (Aqua green)

Device Name: Nitrile Patient Examination Gloves

Device Classification Name: Patient Examination Gloves

Device Class: Class I

Product code LZA

4. Device Description:

Medcare Powder-Free Blue Nitrile Patient Examination Gloves are non-sterile, single use, disposable gloves intended for medical purposes to be worn on the hands of examiners to prevent contamination between a patient and an examiner. The gloves are nitrile, powder- free, ambidextrous, and blue-colored with a beaded cuff. The proposed device is offered in the following sizes:

Module number	Size
MD0120S	S
MD0120M	M
MD0120L	L
MD0120XL	XL

5. Indications for Use:

The powder free patient examination gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner. The device is for over the counter use.

6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Comparison Chart

Item	Acceptance Criteria	Subject Devices Medcare Powder-Free Blue Nitrile Patient Examination Gloves K211808	Predicate Device Powder Free Nitrile Examination Glove (Aqua green) K200326	Same, Similar or Different
Product Code	LZA	LZA	LZA	Same
Intended Use/Indications for Use	---	The powder free patient examination gloves are disposable devices intended for medical purposes that are worn	The Powder Free Nitrile Examination Glove (Aqua Green) is a disposable device intended for Medical	Similar*

		on the examiner's hand to prevent contamination between patient and examiner. The device is for over the counter use.	purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.	
Color	---	Blue	Aqua Green	Different*
Materials	ASTMD6910-10 (Reapproved 2015)	Nitrile	Nitrile	Same
Sterility	---	Non-sterile	Non-sterile	Same
Single Use	---	Yes	Yes	Same
Dimensions (mm)	Overall Length Min 230mm Width (±5mm) Size S = 85mm Size M= 95mm Size L = 105mm Size XL = 115mm Thickness at Palm Min; 0.05 mm Thickness at Finger Tip Min 0.05 mm	Meets ASTM D6319-10	Meets ASTM D6319-10	Same
Physical properties	Before Ageing Tensile Strength (MPa) Min 14min Ultimate Elongation (%) = 500min After Aging at 70oC for 168 hrs @ 100oC for 22 hrs Tensile Strength (MPa)	Meets ASTM D6319-10	Meets ASTM D6319-10	Same

	= 14min Ultimate Elongation (%) = 400min			
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06	Same
Residual Powder	< 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06	Same
Biocompatibility				
Cytotoxicity ISO 10993-5 Tests for in vitro cytotoxicity of medical devices	Non-cytotoxic	Pass	Pass	Same
Irritation ISO 10993-10 Tests for irritation and skin sensitization	Non-Irritating	Pass	Pass	Same
Sensitization ISO 10993-10 Tests for irritation and skin sensitization	Non-sensitizing	Pass	Pass	Same

*The items marked different and similar only differ in color and grammatical structure. These differences do not affect the overall substantial equivalence comparison as the former can be shown in the biocompatibility reports.

7. Summary of Non-Clinical Tests Performed:

The following National and International Standards were utilized for testing the subject device:

- ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application

• ASTM D6124-06 (Reaffirmation 2011) Standard Test Method for Residual Powder on Medical Gloves
• ASTM D5151-06 (Reapproved 2011) Standard Test Method for Detection of Holes in Medical Gloves

• ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
• ISO 10993-05:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

Test Method	**Purpose**	**Acceptance Criteria**	**Result**
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 230 mm for all sizes (±5mm)	Small: Pass Medium: Pass Large: Pass X-Large: Pass
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Small: 85mm Medium: 95mm Large: 105mm X-Large: 115mm	Small: Pass Medium: Pass Large: Pass X-Large: Pass

Test Method	**Purpose**	**Acceptance Criteria**	**Result**		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	Size Small Medium Large X-large	Palm Pass	Finger Pass
ASTM D6319-19 Standard Specification physical properties- for Nitrile Examination Gloves Ultimate Elongation for Medical	To Determine the physical properties Tensile strength	**Before Ageing** Tensile Strength 14Mpa Min for all sizes	Size Small Medium	 Pass	 Pass

Application		**After Ageing** Tensile Strength 14Mpa Min for all size	Large X-large		
	To Determine the physical properties Ultimate Elongation	Before Ageing Ultimate Elongation 500% Min for all Size After Ageing Ultimate Elongation 400% Min for all sizes	Size Small Medium Large X-large	Before ageing Pass	After ageing Pass

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	Pass	
ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 Mg/Glove Max	Size Small Medium Large X-Large	Residual Powder Content Pass

Test Method	**Purpose**	**Acceptance Criteria**	**Result**
ISO 10993-10:2010 Biological Evaluation of	To determine the potential of the material under test to produce	Under the condition of study not an irritant	Under the condition of study not an irritant

Medical Devices Test for Irritation and Skin Sensitization. Test done for irritation.	dermal irritation in Rabbits		
ISO10993-10:2010 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done Skin sensitization.	To determine the skin sensitization potential of the material both in terms of induction and elicitation in Guinea Pig.	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer
ISO 10993-5:2009 biological evaluation of medical devices - part 5, tests for in vitro cytotoxicity.	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method.	Under the conditions of study non cytotoxic	Under the conditions of the study non cytotoxic.

8. Discussion of Clinical Tests Performed:

Not applicable – Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9. Conclusions:

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Medcare Powder-Free Blue Nitrile Patient Examination Gloves are as safe, effective, and perform as well as or better than the legally marketed predicate device cleared under K200326**.**