April 13, 2018

Mercator Medical (Thailand) LTD.
Dariusz Krezymon
Managing Director
88/2 Moo 12 Tambon Kampaengphet
Amphur Rattaphum, Thailand

Re: K172930
Trade/Device Name: mCare Powder-free Nitrile Blue Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: March 16, 2018
Received: March 23, 2018

Dear Dariusz Krezymon:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172930

Device Name

mCare® Powder Free Nitrile Blue Examination Glove

Indications for Use *(Describe)*

mCare® Powder Free Nitrile Blue Examination Glove 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.

MERCATOR MEDICAL

510(k) SUMMARY

K172930

Powder Free Nitrile Blue Examination Gloves

1.0 Submitter :

Name : Dariusz Jan Krezymon (Mr.)

Address : Mercator Medical (Thailand) LTD.
88/8 Moo 12, Tambon Kampaengphet Amphur Rattaphum,
Songkhla 90180. Thailand

Phone Number : +66 74 584 222

Fax Number : +66 74 584 223

Date: April 11, 2018

2.0 Name of Device :

mCare® Powder-free Nitrile Blue Examination Gloves

Common Name : Nitrile Blue Powder Free Examination Gloves

Classification Name : Patient Examination Gloves

3.0 Identification of The Legally Marketed Devices that equivalency is claimed:

MEDTEXX Blue Color Powder Free Nitrile Rubber Examination Gloves, 510(k): K022548

Regulatory Class I

Product Code : LZA

4.0 Description of The Device :

mCare® Powder-free Nitrile Blue Examination Gloves are substantially equivalent to the Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR 880.6250).

They meet all the current specifications listed under the ASTM Specification D 6319 -10, Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from acrylonitrile-butadiene copolymer dispersion.

These gloves are blue in color and are powder free.

5.0 Intended Use of the Device :

mCare® Powder-free Nitrile Blue Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device :

The mCare® Powder-free Nitrile Blue Examination Gloves, Non-Sterile are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
510(k) Number		K022548	K172930
Name of Device		Blue Powder Free Nitrile Patient Examination Glove	mCare® Powder-free Nitrile Blue Examination Gloves
Dimensions	ASTM D6319-10	Length min 230 mm. Width min 95 ± 10	Length min 230 mm. Width min 95 ± 10
Physical Properties	ASTM D6319-10	**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 %
Thickness	ASTM D6319-10	Finger min 0.05 mm. Palm min 0.05 mm.	Finger min 0.05 mm. Palm min 0.05 mm.
Powder Free	ASTM D6319-06	≤ 2 mg/glove	≤ 2 mg/glove
Biocompatibility	Primary Skin Irritation - ISO 10993-10:2010 (E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant
	Dermal Sensitization – ISO 10993-10:2010 (E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500.3(c) (4)	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
Watertight (1000 ml.)	ASTM D6319-06	AQL 2.5	AQL 2.5
Intended 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.	A 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.
Material	ASTM D6319-10	Nitrile	Nitrile
Color	-	Blue	Blue
Texture	-	Finger texture	Finger texture
Size	Medical Glove Guidance Manual -Labeling	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Glove Guidance Manual -Labeling	Single Use	Single Use
Manufacturer(s)	-	LATEXX Manufacturing,	Mercator Medical (Thailand) LTD.
Conclusion			Similar

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods its meets the ASTM standards.

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above (ASTM Requirements).

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

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

9.0 Conclusion

mCare® Powder-free Nitrile Blue Examination Gloves performs according to the gloves performance standards referenced in section 6.0 above and meet ASTM standards. Consequently, the device is as safe and as effective and performs as well as or better than the predicate device.