DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 4, 2016

Healthy Glove Co., Ltd.
Teoh Shee
Managing Director
119 Kanchanavanich Road, Tambol Patong
Hat Yai, Songkhla 90230
THIALAND

Re: K152479
Trade/Device Name: HG PRO® Nitrile Powder Free Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 15, 2016
Received: March 7, 2016

Dear Mr. Shee:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152479

Device Name
HG PRO® Nitrile Powder Free Examination Gloves

Indications for Use *(Describe)*
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.

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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SRITONG GROUP

510(k) SUMMARY
HG PRO® Nitrile Powder Free Examination Gloves

1.0 Submitter:

Applicant:	Healthy Glove Co., Ltd 119 Kanchanavanich Road, Tambol Patong Hat Yai, Songkhla 90230 Thailand
Phone Number:	+66 74 536 815
Fax Number:	+66 74 536 816
Name of Contact Person:	Teoh, Choh Shee
Preparation date:	January 15, 2016

2.0 Name of Device:

Trade/Proprietary Name(s):	HG PRO® Nitrile Powder Free Examination Gloves
Common Name:	Patient Examination Glove
Classification Name:	Patient Examination Gloves (21 CFR 880.6250 product code LZA)
Device Class:	I

3.0 Identification of The Legally Marketed Devices that equivalency is claimed

Device Name:	MEDTEXX™ Blue Colour Powder Free Nitrile Rubber Examination Glove
Manufacturer:	Latexx Manufacturing Sdn., Bhd
510(k):	K022548
MDL:	-
Regulatory Class:	I
Product Code:	LZA

4.0 Description of the Device:

HG PRO® Nitrile Powder Free Examination Gloves are substantially equivalent to the Class 1 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:

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.

6.0 Summary of Technological Characteristics Compared to the Predicate Device:

There are no different technological characteristics of the Subject Device compared to the Predicate Device.

HG PRO® Nitrile Powder Free Examination Gloves are summarized with the following technological characteristics compared to ASTM D 6319 or equivalent standards as shown in Table 1.

Table 1. Side-by-Side Comparison of Predicate Device with Subject Device: Indication for Use, Non-clinical Performance Data and Technological Characteristics

Characteristics	**Reference/Standards**	**Predicate: K022548** Non-Sterile, Powder Free Nitrile Examination glove	**Subject Device:** **New 510(k) submission** Non-Sterile, Powder Free Nitrile Examination glove
Manufacturer(s)	-	Latexx Manufacturing Sdn., Bhd.	Healthy Glove Co., Ltd
Indication for Use	Medical Gloves Guidance Manual	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	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 Synthetic Rubber	Nitrile Synthetic Rubber
Color	-	Blue	Blue
Texture	-	Textured Fingers	Textured Fingers
Size	Medical Glove Guidance Manual-Labeling- Issued on January 22, 2008	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Gloves Guidance Manual -Issued on January 22, 2008	Single use	Single use

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Characteristics	**Acceptance Criteria/Standards**	**Predicate: K022548** Non-Sterile, Powder Free Nitrile Examination glove	**Subject Device: New 510(k) submission** Non-Sterile, Powder Free Nitrile Examination glove
Dimension	ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10 ***Length*** Extra Small = 220 mm minimum Small = 220 mm minimum Medium = 230 mm minimum Large = 230 mm minimum Extra Large = 230 mm minimum ***Palm Width*** Extra Small = 60-80 mm Small = 70-90 mm Medium = 85-105 mm Large = 100-120 mm Extra Large = 110-130 mm
Thickness	ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10 Finger: 0.05 mm min Palm: 0.05 mm min
Physical Properties	ASTM D6319-10	Meet ASTM D6319-10	Meet ASTM D6319-10 *Tensile Strength:* 14 MPa min (before aging) 14 MPa min (after aging) *Ultimate Elongation:* 500% min (before aging) 400% min (after aging)
Watertight test (1000 ml)	ASTM D5151-06	Pass	Pass AQL 1.5
Residual Powder	ASTM D6124-06	Meet ≤ 2.0 mg/glove	Meet ≤ 2.0 mg/glove
Biocompatibility	Primary Skin Irritation - ISO 10993-10: 2010	Pass	Pass Not a primary skin irritant under the conditions of the study
	Dermal Sensitization - ISO 10993-10: 2010	Pass	Pass Not a contact sensitizer under the conditions of the study

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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 in the previous section (ASTM Requirements).

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

No Clinical testing was required to determine substantial equivalence of this device.

9.0 Conclusion:

Based on the comparison of the intended use, technological characteristics and non-clinical performance test data, the Subject Device HG PRO® Nitrile Powder Free Examination Glove is substantially equivalent to the Predicate Device K022548