December 17, 2021

Hycare International Co., Ltd
Sebastian Feye
Regulatory Affairs Consultant
Accurate Consulting Inc.
3234 Ibis Street
San Diego, California 92103

Re: K211209
Trade/Device Name: Hycare Med+ Nitrile Examination Gloves; Hycare Touch Latex Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LYY
Dated: November 1, 2021
Received: November 4, 2021

Dear Sebastian Feye:

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)*
K211209

Device Name
Hycare Touch Latex 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 hands or finger to prevent contamination between patient and examiner.

Model LWH-0201 - Latex examination gloves non-sterile powder-free polymer coated (Ambidextrous) – palm textured – - Color: Natural White - Sizes: X-Small, Small, Medium, Large and X-Large

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.

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)*
K211209

Device Name
Hycare Med+ Nitrile 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 hands or finger to prevent contamination between patient and examiner.

Model NBL-0201 - Nitrile examination gloves non-sterile powder-free (Ambidextrous) – Finger textured - Color: Blue - Sizes: Small, Medium, Large, X-Large and XX Large

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.

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510(k) Summary – K211209

1 SUBMITTER:

Tippawan Phongpheaw, Assistant Managing Director
Hycare International Co., Ltd
1197 Moo 3, Asia Highway, Khuanlang Hatyai
Songkhla, 90110 Thailand
Establishment Registration Number: None

Primary Contact:
Sebastian Feye, Regulatory Affairs Consultant
Accurate Consultants Inc.
3234 Ibis Street
San Diego, CA, 92103
Telephone: 619-517-0673
sebastian@accuratefdaconsulting.com

Date Prepared: 12/16/2021

2 DEVICE:

Name of Device Candidate #1:

1) Hycare Med+ Nitrile Examination Gloves

Common or Usual Name: Exam Gloves

Classification Name: Patient Examination Gloves (21 CFR 880.6250)

Regulatory Class: 1, reserved

Product code: LZA

Name of Device Candidate #2:

2) Hycare Touch Latex Examination Gloves

Common or Usual Name: Exam Gloves

Classification Name: Patient Examination Gloves (21 CFR 880.6250)

Regulatory Class: 1, reserved

Product code: LYY

3 PREDICATE DEVICES:

Candidate #1	Primary Predicate	Manufacturer	Docket Number
Hycare Med+ Nitrile Examination Gloves	Powder Free Nitrile Patient Exam Gloves,	Tangshan Zhonghong Pulin Plastic Co., Ltd	K120970

Candidate #2	Primary Predicate	Manufacturer	Docket Number
Hycare Touch Latex Examination Gloves	Powder Free Latex Exam Glove, with Protein Labeling (50 ug/g or less)	Hycare International Co., Ltd	K020042

4. DEVICE DESCRIPTION:

Two subject devices are bundled into this 510(k) submission. The first is a Hycare Med+ Nitrile Examination Gloves, blue colored, non-sterile called Hycare Med+ Nitrile Examination Gloves and the second is Hycare Touch Latex Examination Gloves, Natural White, Non-Sterile with Protein Labeling Claim (50 ug/g or less) called Hycare Touch Latex Examination Gloves.

The principal operation both types of patient exam gloves are to provide single use barrier protection for the wearer and each device meets all the appropriate requirement specifications for Barrier Protection and tensile properties as defined in ASTM D6319-10, Standard Specification for Nitrile Examination Gloves and ASTM D3578-19, Standard Specification for Rubber Examination Gloves.

The following models are disposable, single-use examination gloves (in boxes of 50, 100 and 200) which are included in this submission:

Models	Description	Length	Color	Sizes

	Hycare Touch Latex Examination Gloves			
LWH-0201	Latex examination gloves non-sterile powder-free polymer coated (Ambidextrous) – palm textured	min 240 mm	Natural white	XS,S,M,L,XL
	Hycare Med+ Nitrile Examination Gloves			
NBL-0201	Nitrile examination gloves non-sterile powder-free (Ambidextrous) – Finger textured	min 240 mm	Blue	S,M,L,XL, XXL

5 INDICATIONS FOR USE:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The following tables compares each subject device and it's predicate device, that are identified in Section 3.0 of this summary:

Candidate #1

Characteristics	**Subject device,** Hycare Med+ Nitrile Examination Gloves	**Predicate Device** Tangshan Zhonghong Pulin Plastic Co. Powder- Free Nitrile Patient Exam Glove	**Comments**
510k	K211209	**K120970**	Different
Product Code	LZA	LZA	Same
Intended Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands 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 hands or finger to prevent contamination between patient and examiner.	Same
Material Use	Nitrile Compound	Nitrile Compound	Same
Color	Blue	Blue	Same
Sterility	Non-sterile	Non-sterile	Same

Dimensions	Overall Length (mm) Min 230mm Width (± 10mm) Size S = 80mm Size M= 95mm Size L = 110mm Size XL = 120mm XXL = 130 mm Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Overall Length (mm) Min 230mm Width (± 10mm) Size S = 80mm Size M= 95mm Size L = 110mm Size XL = 120mm Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Meets ASTM D6319-10
Physical Properties	Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min After Aging at 70oC for 168 hrs @ 100oC for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min After Aging at 70oC for 168 hrs @ 100oC for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10
Freedom from Pinholes	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-19
Residual Powder	< 2.0 mg/dm2	< 2.0 mg/dm2	Meets ASTM D6124-06
Biocompatibility - ISO 10993-10- -Primary Skin Irritation Test	Under the conditions of this study, the test article was a nonirritant.	Under the conditions of this study, the test article was a nonirritant.	Meets ISO 10993-10
ISO 10993-10- Dermal Sensitization Assay	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	Meets ISO 10993-10
ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	Under the conditions of this study, the test article was cytotoxic; does not meet ISO 10993-5	Did not conduct this testing	Different
ISO 10993-11- Systemic Toxicity	Under the conditions of this study, the test article did not induce systemic toxicity; meets ISO 10993-11	Did not conduct this testing	Different

Labeling for the legally marketed device to which substantial equivalence is claimed	Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non-sterile	Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non-sterile	Same

There are no significant differences between the Hycare International Nitrile examination gloves non-sterile powder-free and the predicate, **Tangshan Zhonghong Pulin Plastic Co** Powder-Free Nitrile Patient Examination Gloves. (**K120970)**

Candidate #2

Characteristics	**Subject device,** Hycare Touch Latex Examination Gloves	**Predicate Device** Hycare International Co., Ltd Powder-Free Latex Exam Gloves With Protein Labeling (50 ug/g or less	**Comments**
510k	K211209	**K020042**	Different
Product Code	LYY	LYY	Same
Intended Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands 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 hands or finger to prevent contamination between patient and examiner.	Same
Material Use	Rubber (Latex) Compound	Rubber (Latex) Compound	Same
Color	Natural White	Natural White	Same
Sterility	Non-sterile	Non-sterile	Same
Dimensions	Overall Length (mm) Min 220-230 mm Width (± 10 mm) Size XS = 70mm Size S = 80mm Size M= 95mm Size L = 110mm Size XL = 120 mm Thickness at Palm (mm) Min; 0.08 mm Thickness at Finger Tip (mm) Min 0.08 mm	Overall Length (mm) Min 220-230 mm Width (± 10 mm) Size XS = 70mm Size S = 80mm Size M= 95mm Size L = 110mm Size XL = 120 mm Thickness at Palm (mm) Min; 0.08+ mm Thickness at Finger Tip (mm) Min 0.08+ mm	Meets ASTM D3578-19

Physical Properties	Before Aging Tensile Strength (MPa) = 18min Ultimate Elongation (%) = 650min Stress at 500% elongation = max 5.5 MPa After Aging at 70oC for 168 hrs @ 100oC for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min	Before Aging Tensile Strength (MPa) = 18min Ultimate Elongation (%) = 650min Stress at 500% elongation = max 5.5 MPa After Aging at 70oC for 168 hrs @ 100oC for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min	Meets ASTM D3578-19
Freedom from Pinholes	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-19
Residual Powder	< 2.0 mg/dm^2	< 2.0 mg/dm2	Meets ASTM D6124-06
Biocompatibility - ISO 10993-10- -Primary Skin Irritation Test	Under the conditions of this study, the test article was a nonirritant.	Under the conditions of this study, the test article was a nonirritant.	Meets ISO 10993-10
ISO 10993-10- Dermal Sensitization Assay	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	Meets ISO 10993-10
ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	Under the conditions of this study, the test article was cytotoxic; does not meet ISO 10993-5	Did not conduct this testing	Different
ISO 10993-11- Systemic Toxicity	Under the conditions of this study, the test article did not induce systemic toxicity; meets ISO 10993-11	Did not conduct this testing	Different
Labeling for the legally marketed device to which substantial equivalence is claimed	Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Natural White - Non-sterile	Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Natural White - Non-sterile	Same

There are no differences between the Hycare Touch Latex Examination Gloves and the predicate device, Hycare International Co., Ltd Powder-Free Latex Exam Gloves with Protein Labeling (50 ug/g or less (K020042).

7 SUMMARY OF NON-CLINICAL TESTING RESULTS

Candidate #1

Hycare Med+ Nitrile Examination Gloves was tested and conformed to the following standards:

Test Title	Purpose of Test	Acceptance Criteria	Results
ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine tensile strength and elongation of gloves	Before Aging: 14 MPa min Tensile, 500% Elongation After Aging: 14 MPa min Tensile, 400% Elongation	Met acceptance criteria after Aging at 70oC for 168 hrs @ 100oC for 22 hrs, Pass
ASTM D5151 Standard Test Method for detection of Holes in Medical Gloves	Pinhole testing with limited number of rejections to ensure physical strength	Inspection level G-1, AQL 2.5, reject max of 22 samples	19 rejects detected, under 22 by AQL standards, Pass
D6124-06 Standard Test Method for Residual Powder on Medical Gloves	To determine residual powder on gloves to ensure under 2.0 mg limit	Residue limit < 2.0 mg on all sizes	All powder residue on all sizes was < 2.0mg, Pass
ISO 10993-10 Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization	To determine irritation and skin sensitization reactions if any	Sensitization: Grades of <1, no evidence of sensitization Skin Irritation: Test sites should not exceed control site grade	Grade 0 for all tests, Pass
ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	To determine if text article is cytotoxic	Cytotoxicity Grade < 2 at undiluted extraction Non-Toxic to L-929 cells	Cytotoxic at undiluted extraction, Failed

Test Title	Purpose of Test	Acceptance Criteria	Results
Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity, ISO 10993-11	To determine if test article does not induce systemic toxicity	1. None of the animals treated with test item should show a significantly greater biological reactivity than animals treated with solvent control. 2. None of the animals in the control group should show significant loss of body weight greater than 10%. 3. No mortality or abnormal behavior such as convulsions or prostration should occur in control group animals.	No mortality or morbidity observed, gradual increase in body weight and no signs of ill health or toxicity was observed, Passed

Candidate #2

Hycare Touch Latex Examination Gloves was tested and conformed to the following standards:

Test Title	Purpose of Test	Acceptance Criteria	Results
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine tensile strength and elongation of gloves	Before Aging: 18 MPa min Tensile, 650% Elongation, 5.5 MPa max at 500% Elongation After Aging: 14 MPa min Tensile, 500% Elongation	Met acceptance criteria after Aging at 70oC for 168 hrs @ 100oC for 22 hrs, Pass
ASTM D5151 Standard Test Method for detection of Holes in Medical Gloves	Pinhole testing with limited number of rejections to ensure physical strength	Inspection level G-1, AQL 2.5	13 rejects detected, under 22 by AQL standards, Pass Pass
D6124-06 Standard Test Method for Residual Powder on Medical Gloves	To determine residual powder on gloves to ensure under 2.0 mg limit	Residue limit < 2.0 mg on all sizes	All powder residue on all sizes was < 2.0mg, Pass

Test Title	Purpose of Test	Acceptance Criteria	Results
ISO 10993-10 Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization	To determine irritation and skin sensitization reactions if any	Sensitization: Grades of <1, no evidence of sensitization Skin Irritation: Test sites should not exceed control site grade	Grade 0 for all tests, Pass
ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	To determine if text article is cytotoxic	Cytotoxicity Grade < 2 at undiluted extraction Non-Toxic to L-929 cells	Cytotoxic at undiluted extraction, Failed
Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity, ISO 10993-11	To determine if test article does not induce systemic toxicity	1. None of the animals treated with test item should show a significantly greater biological reactivity than animals treated with solvent control. 2. None of the animals in the control group should show significant loss of body weight greater than 10%. 3. No mortality or abnormal behavior such as convulsions or prostration should occur in control group animals.	No mortality or morbidity observed, gradual increase in body weight and no signs of ill health or toxicity was observed, Passed

8 SUMMARY OF CLINICAL PERFORMANCE TESTING:

N/A Not applicable for this device.

CONCLUSIONS:

The conclusions drawn from the nonclinical tests that demonstrate that the two devices in this submission, Hycare Med+ Nitrile Examination Gloves (Candidate #1) and the Hycare Touch Latex Examination Gloves (Candidate #2) is as safe, as effective, and performs as well as or better than the legally marketed device.