May 26, 2021

Nautilus Gloves LLC
Mesh Gelman
Owner
767 5th Avenue 15th Floor
Manhattan, New York 10153

Re: K210496
Trade/Device Name: Nautilus Nitrile Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 16, 2021
Received: February 24, 2021

Dear Mesh Gelman:

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
Acting 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)*
K210496

Device Name
Nautilus Nitrile Exam Gloves

Indications for Use *(Describe)*
The Nautilus Nitrile Exam Glove is a non-sterile, 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.

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.

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"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."

SECTION 5: 510(K) SUMMARY

As required by 21 CFR 807.92(c)

Submitter's Name and Address:

Nautilus Gloves LLC
767 5th Avenue 15th Floor
Manhattan, NY 10153
USA
Owner / Operator 10080576

Owner's Name and Information

Nautilus Gloves LLC
767 5th Avenue 15th Floor
Manhattan, NY 10153
USA
Owner / Operator Number: 10080576

Contact Name and Information:

Mesh Gelman
767 5th Avenue 15th Floor
Manhattan, NY 10153
USA

Phone: 646-283-6334
Email: mesh@twocanoes.io

Date Prepared:

February 16, 2021/ Amended April 23, 2021

Device Information:

Device:	Polymer Patient Examination Glove
Trade Name:	Nautilus Nitrile Exam Gloves
Classification:	Surgical and Infection Control Devices (OHT4)
Establishment Registration:	Owner / Operator 10080576
Regulatory Class:	Class I (general controls)
Review Panel:	General Hospital and Personal Use Devices
Product Code:	LZA
Regulation Number:	21 CFR §880.6250

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K182600	Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs	Better Care Plastic Technology Co., Ltd.

Device Description:

Nautilus Nitrile Exam Glove are single use only, non-sterile disposable gloves. The powder-free gloves are made of synthetic copolymer of acrylonitrile and butadiene with a color additive. The gloves are available in small (S), medium (M), large (L), and extra-large (XL).

Indications for Use:
The Nautilus Nitrile Exam Glove is a non-sterile, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Technological Characteristics:
Nautilus Nitrile Exam Gloves provide physical barrier protection from transfer of microorganisms, bodily fluids, and particulate material.

Feature	Predicate Device	Subject Device	Comparison
Product Code	LZA, LZC	LZA	Same
Material Composition	Nitrile	Nitrile	Same
Sizes	S, M, L, XL	S, M, L, XL	Same
Feature	Ambidextrous	Ambidextrous	Same
Residual Powder	Meets	Meets	Same
Biocompatibility per ISO 10993-10	Irritation - Meets Sensitization - Meets	Irritation - Meets Sensitization - Meets	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Color	Blue	Blue	Similar
Intended Use	A patient examination glove is a disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. List of chemotherapy drugs noted on label.	The Nautilus Nitrile Exam Glove is a non-sterile, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Subject Device is not tested or labeled for chemotherapy. Comparison is to the LZA Product Code of Predicate Device.

Performance Functional and Safety Testing:
Bench and laboratory testing was conducted to demonstrate the performance of the Nautilus Nitrile Exam Gloves. The tests results demonstrated that the proposed device met all the required design specifications and performance standards utilizing the following test methods, standards, and specifications:

Test Methodology	Purpose		Acceptance Criteria	Results
ASTM D6319	Length	S	≥ 220 mm	Pass
		M, L, XL	≥ 230 mm	Pass
	Palm Width	S	80±10 mm	Pass
		M	95±10 mm	Pass
		L	110±10 mm	Pass
		XL	120±10 mm	Pass
	Finger Thickness		≥ 0.05 mm	Pass
	Palm Thickness		≥ 0.05 mm	Pass
ASTM D5151	Detection of Pin Holes		Product shall be free of pin holes under the conditions of the test	Pass
ASTM D6124	Residual Powder		≤2.0 mg	Pass
ASTM D7160	Tensile (Pre Aging)		≥ 14 MPa	Pass
	Tensile (Post Aging)		≥ 14 MPa	Pass
	Elongation (Pre-Aging)		≥ 500 %	Pass
	Elongation (Post-Aging)		≥ 400 %	Pass
ISO 10993-5 ISO 10993-12 MTT Method	Biocompatibility: Cytotoxicity		Under the conditions of this study, the test article shall have no potential toxicity to L-929 cells	Pass
ISO 10993-1 ISO 10993-10 Guinea Pig Maximization	Biocompatibility: Skin Sensitization		The test article shall show no evidence of causing delayed dermal contact sensitization in the guinea pig.	Pass
ISO 10993-10 Extraction Method	Biocompatibility: Skin Irritation		The response of the test article extract shall be categorized as negligible under the test condition.	Pass

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151-2006 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D7160-05/R2010 Standard Practice for Determination of Expiration Dating for Medical Gloves
- ASTM D6124 Standard Test Method for Residual Powder On Medical Gloves
- ISO 10993-10:2013 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity

Conclusion:

The conclusions drawn from the nonclinical demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device