June 26, 2019

O & M Halyard, Inc.
Angela Bunn
Director Regulatory Affairs
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K182851
Trade/Device Name: SkyBreeze Zero Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: May 23, 2019
Received: May 24, 2019

Dear Angela Bunn:

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 Elizabeth Claverie-Williams, M.S.
Assistant Director
THT4B2: Disinfection, Reprocessing and Personal Protection
Acting Assistant Director, THT4B1: Sterility Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182851

Device Name
SkyBreeze Zero Nitrile Powder-Free Exam Gloves, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*

The Skybreeze Zero Nitrile Powder-Free Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with the following chemotherapy drugs:

Tested Chemotherapy Drugs and Concentration	Average Breakthrough Detection Time (Minutes)
• Cyclophosphamide (20.0 mg/ml)	No breakthrough up to 240 minutes
• Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
• Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
• 5-Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
• Paclitaxel (Taxol) (6.0 mg/ml)	No breakthrough up to 240 minutes
• Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
• Dacarbazine (10.0 mg/ml)	No breakthrough up to 240 minutes
• Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
• Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
• Vincristine sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
• Carmustine (3.3 mg/ml)	No breakthrough up to 18.6 minutes
• ThioTEPA (10.0 mg.ml)	No breakthrough up to 48.3 minutes

Warning: Not for Use with: Carmustine, ThioTEPA

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

Date Summary was Prepared	June 25, 2019
510(k) Submitter	O & M Halyard, Inc. 5405 Windward Parkway Alpharetta, GA 20004
Primary Contact for this 510(k) Submission	Angela L. Bunn, Director Regulatory Affairs O & M Halyard, Inc. 5405 Windward Parkway, Alpharetta, GA 30004 US (470) 448-5158 [voice] angela.bunn@hyh.com
Device Trade Name	SkyBreeze Zero Nitrile Powder-Free Exam Gloves, Tested for Use with Chemotherapy Drugs
Device Common Name	Medical Exam Gloves
Device Product Code and Classification Name	LZA, LZC Class I, 21 CFR §880.6250 Patient Examination Glove
Predicate Device	K180646 Halyard Lavender Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs
Subject Device Description	The SkyBreeze Zero Nitrile Powder-Free Exam Gloves, Tested for Use with Chemotherapy Drugs are disposable, blue-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves packed in a cardboard dispenser box. The Device follows consensus standards: • ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves • ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications • ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves • ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs • ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for Systemic Toxicity • ISO 10993-10: 2010: Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization

Indications for Use	The Skybreeze Zero Nitrile Powder-Free Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with the following chemotherapy drugs: • Cyclophosphamide (20.0 mg/ml) No breakthrough up to 240 minutes • Doxorubicin HCl (2.0 mg/ml) No breakthrough up to 240 minutes • Etoposide (20.0 mg/ml) No breakthrough up to 240 minutes • 5-Fluorouracil (50.0 mg/ml) No breakthrough up to 240 minutes • Paclitaxel (Taxol) (6.0 mg/ml) No breakthrough up to 240 minutes • Cisplatin (1.0 mg/ml) No breakthrough up to 240 minutes • Dacarbazine (10.0 mg/ml) No breakthrough up to 240 minutes • Ifosfamide (50.0 mg/ml) No breakthrough up to 240 minutes • Mitoxantrone (2.0 mg/ml) No breakthrough up to 240 minutes • Vincristine sulfate (1.0 mg/ml) No breakthrough up to 240 minutes • Carmustine (3.3 mg/ml) No breakthrough up to 18.6 minutes • ThioTEPA (10.0 mg.ml) No breakthrough up to 48.3 minutes Warning: Not for Use with: Carmustine, ThioTEPA
Summary of comparison of technological characteristics	Both the subject device and the predicate device are powder-free non-sterile nitrile exam gloves tested for resistance to permeation by chemotherapy drugs.

Technological Characteristics Comparison Table

	Subject Device	**Predicate Device K180646**	**Comparison**
FDA Product Code	LZC, LZA	LZC, LZA	Same
FDA Classification	Class I	Class I	Same
Regulation Number	880.6250	880.6250	Same
Common Name	Medical Exam Glove	Medical Exam Glove	Same
Device Trade Name	SkyBreeze Zero Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs	Halyard Lavender Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs	Similar
Intended Use	The Skybreeze Zero Nitrile Powder-Free Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs listed on the label.	The Halyard Lavender Nitrile-Powder-Free Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs listed on the label.	Same

Technological Characteristics	Blue-colored, 9.5-inch, 0.07 mm thick at palm, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	Lavender-colored, 9.5-inch, .058 mm thick at palm, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	Similar
Sizes of gloves	Extra Small (XS) Small (S) Medium (M) Large (L) Extra Large (XL)	Extra Small (XS) Small (S) Medium (M) Large (L) Extra Large (XL)	Similar dimensions with minor differences in fingers and palm thickness.
Thickness at Fingers	0.10 mm (XS) 0.10 mm (S) 0.10 mm (MS) 0.10 mm (L) 0.10 mm (XL)	0.078 mm (XS) 0.078 (S) 0.078 mm (MS) 0.078 mm (L) 0.078 mm (XL)	
Thickness at Palm	0.07 mm (XS) 0.07 mm (S) 0.07 mm (M) 0.07 mm (L) 0.07 mm (XL)	0.058 (XS) 0.058 (S) 0.058 (M) 0.058 (L) 0.058 (XL)	
Width of Palm	70 mm (XS) 80 mm (S) 95 mm (M) 110 mm (L) 120 mm (XL)	70 mm (XS) 80 mm (S) 95 mm (M) 110 mm (L) 120 mm (XL)	
Length of Palm	240 mm (XS) 240 mm (S) 240 mm (M) 240 mm (L) 240 mm (XL)	242 mm (XS) 242 mm (S) 242 mm (M) 242 mm (L) 242 mm (XL)	
Texture	Textured fingertips	Textured fingertips	Same
Sterility	Non-Sterile	Non-Sterile	Same
Shelf life	No Shelf life is being claimed at this time.	No Shelf life is being claimed at this time.	Same

Biocompatibility	Based ISO 10993 – 11 (2017) Biological evaluation of Medical devices – Test for Systemic Toxicity, the test article was considered non-toxic.	Based ISO 10993 – 11 (2017) Biological evaluation of Medical devices – Test for Systemic Toxicity, the test article was considered non-toxic.	Same
	Based on ISO 10993 – 10 (2010): Under the conditions of the study, not a primary skin irritant; Under conditions of the study, not a contact sensitizer.	Based on ISO 10993 – 10 (2010): Under the conditions of the study, not a primary skin irritant; Under conditions of the study, not a contact sensitizer.	

Performance Data			
Standard	**Results Subject Device**	**Results K180646**	**Remarks**
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Result: Meets acceptance criteria for 10 drugs. No breakthrough up to 240 minutes: Cisplatin (1 mg/ml) No breakthrough up to 240 minutes Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes Etoposide (20 mg/ml) No breakthrough up to 240 minutes Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes Vincrinstine Sulfate (1 mg/ml) No breakthrough up to 240 minutes Carmustine (3.3 mg/ml) showed no signs of breakthrough until 18.6 minutes Thiotepa (10 mg/ml) showed no signs of breakthrough until 48.3 minutes	Result: Meets acceptance criteria for 10 drugs. No breakthrough up to 240 minutes: Cisplatin (1 mg/ml) No breakthrough up to 240 minutes Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes Etoposide (20 mg/ml) No breakthrough up to 240 minutes Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes Vincrinstine Sulfate (1 mg/ml) No breakthrough up to 240 minutes Carmustine (3.3 mg/ml) showed no signs of breakthrough until 0.3 minutes Thiotepa (10 mg/ml) showed no signs of breakthrough until 30.9 minutes.	Similar with different breakthrough times for Carmustine and Thiotepa.

ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves	Testing of the subject device shows it meets the 2.5% AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard.	Testing of the subject device shows it meets the 2.5% AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard.	Same
ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves	Residual powder on the subject device is an average of 0.4 mg/glove within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder- free.	Residual powder on the subject device is an average of 0.4 mg/glove within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder- free.	Same
ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications	The physical dimensions of the subject device are within the limits of the standard and the physical properties of the subject device meet the requirements for tensile strength with an average before aging of 26.17 MPa and after aging of 34.37 MPa and elongation of 580% before aging and 554% after aging.	The physical dimensions of the predicate device are within the limits of the standard and the physical properties meet the requirements for tensile strength with an average before aging of 30.56 MPa and after aging of 37.53 MPa and elongation of 593% before aging and 533% after aging.	Similar
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.		