Halyard Health
Christine Macauley
Regulatory Affairs Technical Leader
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K180646
Trade/Device Name: Halyard Lavender Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZC, LZA
Dated: Jun 11, 2018
Received: June 12, 2018

Dear Christine Macauley:

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 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,

Clarence W. Murray Iii III -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)*
K180646

Device Name
Halyard Lavender Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
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 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 0.3 minutes
ThioTEPA (10.0 mg.ml) No breakthrough up to 30.9 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.

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510(k) Summary-K180646

Date Summary was Prepared	June 26, 2018
510(k) Submitter	Christine L. Macauley Regulatory Affairs Technical Leader Halyard Health, Inc. 5405 Windward Parkway Alpharetta, GA 30004 Email: Chris.Macauley@hyh.com Ph: 470-448-5158
Primary Contact for this 510(k) Submission	Same as above
Device Trade Name	Halyard® Lavender Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs
Device Common Name	Medical Exam Gloves
Device Product Code and Classification Name	LZC Class I, 21 CFR §880.6250 Patient Examination Glove
Predicate Device	K172525 Blue Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs
Reference Device	K081260 Kimberly-Clark Lavender Nitrile Powder-Free Exam Gloves
Subject Device Description	Halyard® Lavender Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs are disposable, lavender-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves that are packed in a cardboard dispenser box. 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 10993-11:2006, 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 Halyard® Lavender Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs 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 0.3 minutes • ThioTEPA (10.0 mg.ml) No breakthrough up to 30.9 minutes **Warning:** Not for Use With: Carmustine, ThioTEPA	
Comparison of Technological Characteristics	**Subject K180646** Lavender-colored, 9.5 inch, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	**Predicate K172525:** Blue-colored, 9.5 inch, nitrile, powder-free, ambidextrous, non-sterile patient examination glove.
Summary of comparison of technological characteristics	There are no different technological characteristics of the subject device compared to the predicate device. They are powder-free non-sterile nitrile exam gloves tested for resistance to permeation by chemotherapy drugs. The predicate device is a different color. This difference does not raise new issues of safety or effectiveness of the subject device.	

Comparison of the Subject Device with the Predicate Device

	Subject Device	**Predicate Device K172525**	**Remarks**
FDA Product Code	LZC	LZC	Same
FDA Classification	Class I	Class I	Same
Common Name	Medical Exam Glove	Medical Exam Glove	Same
Device Trade Name	Halyard Lavender Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs	Blue Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	Similar but different color

Indications for Use	The Halyard Lavender Powder-Free Nitrile 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.	Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Technological Characteristics	Lavender-colored, 9.5 inch, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	Technological characteristics and design meet ASTM D6319-10 and follow the FDA's Medical Glove Guidance Manual.	Similar
Performance Data			
Standard	**Results Subject Device**	**Results K172525**	**Remarks**
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	No signs of breakthrough after 4 hours for 10 drugs. Carmustine showed no signs of breakthrough until 0.3 minutes and Thiotepa showed no signs of breakthrough until 30.9 minutes. Result: Meets acceptance criteria. • 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 0.3 minutes • ThioTEPA (10.0 mg.ml) No breakthrough up to 30.9 minutes	Results from the Permeation data for the predicate device. • 5-Fluorouracil (50.0 mg/ml) No breakthrough up to 240 minutes • Etoposide (20.0 mg/ml) No breakthrough up to 240 minutes • Cyclophosphamide (20.0 mg/ml) No breakthrough up to 240 minutes • Carmustine (3.3 mg/ml) No breakthrough up to 12.4 minutes • ThioTEPA (10.0 mg.ml) No breakthrough up to 24.4 minutes • Paclitaxel (Taxol) (6.0 mg/ml) No breakthrough up to 240 minutes • Doxorubicin HCl (2.0 mg/ml) No breakthrough up to 240 minutes • Dacarbazine (10.0 mg/ml) No breakthrough up to 240 minutes • Cisplatin (1.0 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	Similar

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 with an actual AQL of 1.0%.	Testing results from the Predicate device: In accordance with ASTM D5151-06, following ASTM D6319 AQL 2.5/Inspection Level G-I	Similar
ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves	Residual powder on the subject device is an average of 0.04 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 predicate device is a max of 0.52 mg per glove within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free	Similar

ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications	The physical dimensions of the subject device is 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 30.56 MPa and after aging of 37.53 MPa and elongation of 593% before aging and 533% after aging.	The physical dimensions of the subject device is 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 15 MPa and after aging of 14 MPa and elongation of 500% before aging and 400% after aging.	Similar
Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization	Under the conditions of the study the subject device extracts (polar and non-polar) were not found to cause a sensitizing response or an irritation response in the animal model.	Under the conditions of the study the predicate device extracts (polar and non-polar) were not found to cause a sensitizing response or an irritation response in the animal model.	Same
Biological evaluation of medical devices – Part 11: Tests for Systemic Toxicity	Under the condition of the study the subject device extracts (polar and non-polar) were not found to cause a systemic response in the animal model	Data not available from manufacturer	Different
Conclusion:	Performance data support the conclusion that the subject device is as safe, as effective, and performs as well as the legally marketed device that was submitted and cleared under K172525.		