November 2, 2018

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

Re: K182096
Trade/Device Name: Halyard Purple Nitrile Max Powder-Free Exam Gloves for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZC
Dated: August 2, 2018
Received: August 3, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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)*
K182096

Device Name
Halyard Purple Nitrile Max Powder-Free Exam Gloves for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
The Halyard Purple Nitrile Max 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 the following chemotherapy drugs:

- Arsenic Trioxide (1 mg/ml) No breakthrough up to 240 minutes
- Azacitidine (Vidaza) (25 mg/ml) No breakthrough up to 240 minutes
- Bendamustine (5 mg/ml) No breakthrough up to 240 minutes
- Bortezomib (Velcade) (1 mg/ml) No breakthrough up to 240 minutes
- Bleomycin sulfate (15 mg/ml) No breakthrough up to 240 minutes
- Busulfan (6 mg/ml) No breakthrough up to 240 minutes
- Carboplatin (10 mg/ml) No breakthrough up to 240 minutes
- Carlzomib (2 mg/ml) No breakthrough up to 240 minutes
- Cetuximab (Erbitux) (2 mg/ml) No breakthrough up to 240 minutes
- Cisplatin (1 mg/ml) No breakthrough up to 240 minutes
- Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes
- Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes
- Cytarabine HCL (100 mg/ml) No breakthrough up to 240 minutes
- Cytovene (10 mg/ml) No breakthrough up to 240 minutes
- Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes
- Daunorubicin HCL (5 mg/ml) No breakthrough up to 240 minutes
- Decitabine (5 mg/ml) No breakthrough up to 240 minutes
- Docetaxel (10 mg/ml) No breakthrough up to 240 minutes
- Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes
- Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes
- Etoposide (20 mg/ml) No breakthrough up to 240 minutes
- Fludarabine (25 mg/ml) No breakthrough up to 240 minutes
- Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes
- Fulvestrant (50 mg/ml) No breakthrough up to 240 minutes
- Gemcitabine (38 mg/ml) No breakthrough up to 240 minutes
- Idarubicin (1 mg/ml) No breakthrough up to 240 minutes
- Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes
- Irinotecan (20 mg/ml) No breakthrough up to 240 minutes
- Mechlorethamine HCL (1 mg/ml) No breakthrough up to 240 minutes
- Melphalan (5 mg/ml) No breakthrough up to 240 minutes
- Methotrexate (25 mg/ml) No breakthrough up to 240 minutes
- Mitomycin-C (0.5 mg/ml) No breakthrough up to 240 minutes
- Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes
- Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes
- Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes
- Paraplatin (10 mg/ml) No breakthrough up to 240 minutes
- Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes
- Pertuzumab (30 mg/ml) No breakthrough up to 240 minutes
- Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes
- Retrovir (10 mg/ml) No breakthrough up to 240 minutes

• Rituximab (10 mg/ml) No breakthrough up to 240 minutes
• Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes
• Trastuzumab (21 mg/ml) No breakthrough up to 240 minutes
• ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes
• Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes
• Triclosan (2 mg/ml) No breakthrough up to 240 minutes
• Trisonex (1 mg/ml) No breakthrough up to 240 minutes
• Vincrinstine Sulfate (1 mg/ml) No breakthrough up to 240 minutes
• Vinblastine (1 mg/ml) No breakthrough up to 240 minutes
• Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes
• Zoledronic Acid (0.8 mg/ml
Carmustine (3.3 mg/ml) permeation occurred at 128.5 minutes

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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K182096 510(k) Summary

Date Summary was Prepared	November 1, 2018
Submitter	Owens & Minor Halyard, Inc. 5405 Windward Parkway Alpharetta, GA 30004 USA
Primary Contact for this Submission	Angela L. Bunn, RAC Director Regulatory Affairs Tel: 470-448-5856 Email: angela.bunn@hyh.com
Device Trade Name	Halyard Purple Nitrile Max Powder-Free Exam Gloves for Use with Chemotherapy Drugs
Device Common Name	Patient Examination Glove
Device Product Code and Classification Name	LZC Class I, 21 CFR §880.6250 Patient Examination Glove
Predicate Device	K160709 Halyard Purple Nitrile-Xtra Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs
Subject Device Description	Halyard Purple Nitrile Max Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs are disposable, purple-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves that are packed in a cardboard dispenser box.

Indications for Use	The Halyard Purple Nitrile Max 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: • Arsenic Trioxide (1 mg/ml) No breakthrough up to 240 minutes • Azacitidine (Vidaza) (25 mg/ml) No breakthrough up to 240 minutes • Bendamustine (5 mg/ml) No breakthrough up to 240 minutes • Bortezomib (Velcade) (1 mg/ml) No breakthrough up to 240 minutes • Bleomycin sulfate (15 mg/ml) No breakthrough up to 240 minutes • Busulfan (6 mg/ml) No breakthrough up to 240 minutes • Carboplatin (10 mg/ml) No breakthrough up to 240 minutes • Carlzomib (2 mg/ml) No breakthrough up to 240 minutes • Cetuximab (Erbitux) (2 mg/ml) No breakthrough up to 240 minutes • Cisplatin (1 mg/ml) No breakthrough up to 240 minutes • Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes • Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes • Cytarabine HCL (100 mg/ml) No breakthrough up to 240 minutes • Cytovene (10 mg/ml) No breakthrough up to 240 minutes • Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes • Daunorubicin HCL (5 mg/ml) No breakthrough up to 240 minutes • Decitabine (5 mg/ml) No breakthrough up to 240 minutes • Docetaxel (10 mg/ml) No breakthrough up to 240 minutes • Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes • Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes • Etoposide (20 mg/ml) No breakthrough up to 240 minutes • Fludarabine (25 mg/ml) No breakthrough up to 240 minutes • Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes • Fulvestrant (50 mg/ml) No breakthrough up to 240 minutes • Gemcitabine (38 mg/ml) No breakthrough up to 240 minutes • Idarubicin (1 mg/ml) No breakthrough up to 240 minutes • Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes • Irinotecan (20 mg/ml) No breakthrough up to 240 minutes • Mechlorethamine HCL (1 mg/ml) No breakthrough up to 240 minutes • Melphalan (5 mg/ml) No breakthrough up to 240 minutes • Methotrexate (25 mg/ml) No breakthrough up to 240 minutes • Mitomycin-C (0.5 mg/ml) No breakthrough up to 240 minutes • Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes • Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes • Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes • Paraplatin (10 mg/ml) No breakthrough up to 240 minutes • Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes • Pertuzumab (30 mg/ml) No breakthrough up to 240 minutes • Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes • Retrovir (10 mg/ml) No breakthrough up to 240 minutes • Rituximab (10 mg/ml) No breakthrough up to 240 minutes • Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes • Trastuzumab (21 mg/ml) No breakthrough up to 240 minutes • ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes • Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes • Triclosan (2 mg/ml) No breakthrough up to 240 minutes • Trisonex (1 mg/ml) No breakthrough up to 240 minutes • Vincrinstine Sulfate (1 mg/ml) No breakthrough up to 240 minutes • Vinblastine (1 mg/ml) No breakthrough up to 240 minutes • Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes • Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes **Carmustine (3.3 mg/ml) permeation occurred at 128.5 minutes**

Technological Characteristic Comparison Table	**Subject Device** Purple-colored, 16 inch, 0.24 mm thick at palm, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	**Predicate K160709** Purple-colored, 12 inch, 0.11 mm thick at palm, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.

	Subject Device K182096	**Predicate Device K160709**	**Comparison**
FDA Product Code	LZC	LZC	Same
FDA Classification	Class I	Class I	Same
Common Name	Patient Exam Glove	Patient Exam Gove	Same
Device Trade Name	Halyard Purple Nitrile Max Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs	Halyard Purple Nitrile Xtra Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs	Similar
Intended Use	The Halyard Purple Nitrile Max 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 in the IFU statement.	The Halyard Purple Nitrile-Xtra 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 in the IFU statement.	Same
Technological Characteristics	Purple-colored, 16 inch, 0.24 mm thick at palm, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	Purple-colored, 12 inch, 0.11 mm thick at palm, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	Similar
Performance Data			
Standard	**Results Subject Device**	**Results K160709**	**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 51 drugs. Carmustine showed no signs of breakthrough until 128.5 minutes Result: Meets acceptance criteria. No breakthrough up to 240 minutes: Arsenic Trioxide (1 mg/ml) Azacitidine (Vidaza) (25 mg/ml) Bendamustine (5 mg/ml) Bortezomib (Velcade) (1 mg/ml) Bleomycin sulfate (15 mg/ml) Busulfan (6 mg/ml) Carboplatin (10 mg/ml) Carfilzomib (2 mg/ml) Cetuximab (Erbitux) (2 mg/ml) Cisplatin (1 mg/ml) Cladribine (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCL (100 mg/ml) Cytovene (10 mg/ml) Dacarbazine (10 mg/ml) Daunorubicin HCL (5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCL (2 mg/ml) Ellence (2 mg/ml) Etoposide (20 mg/ml) Fludarabine (25 mg/ml) Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (38 mg/ml) Idarubicin (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan (20 mg/ml) Mechlorethamine HCL (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (2 mg/ml) Paclitaxel (6 mg/ml) Paraplatin (10 mg/ml) Pemetrexed (25 mg/ml) Pertuzumab (30 mg/ml) Raltitrexed (0.5 mg/ml) Retrovir (10 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Trastuzumab (21 mg/ml) ThioTEPA (10 mg/ml) Topotecan HCL (1 mg/ml) Triclosan (2 mg/ml) Trisonex (1 mg/ml) Vincrinstine Sulfate (1 mg/ml) Vinblastine (1 mg/ml) Vinorelbine (10 mg/ml) Zoledronic Acid (0.8 mg/ml) Carmustine (3.3 mg/ml) permeation occurred at 128.5 minutes	No signs of breakthrough after 4 hours for 51 drugs. Carmustine showed no signs of breakthrough until 80.4 minutes Result: Meets acceptance criteria. No breakthrough up to 240 minutes: Arsenic Trioxide (1 mg/ml) Azacitidine (Vidaza) (25 mg/ml) Bendamustine (5 mg/ml) Bortezomib (Velcade) (1 mg/ml) Bleomycin sulfate (15 mg/ml) Busulfan (6 mg/ml) Carboplatin (10 mg/ml) Carfilzomib (2 mg/ml) Cetuximab (Erbitux) (2 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCL (100 mg/ml) Cytovene (10 mg/ml) Dacarbazine (10 mg/ml) Daunorubicin HCL (5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCL (2 mg/ml) Ellence (2 mg/ml) Eribulin Mesylate (0.5 mg/ml) Etoposide (20 mg/ml) Fludarabine (25 mg/ml) Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (38 mg/ml) Idarubicin (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan (20 mg/ml) Mechlorethamine HCL (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (2 mg/ml) Paclitaxel (6 mg/ml) Paraplatin (10 mg/ml) Pemetrexed (25 mg/ml) Pertuzumab (30 mg/ml) Raltitrexed (0.5 mg/ml) Retrovir (10 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Trastuzumab (21 mg/ml) ThioTEPA (10 mg/ml) Topotecan HCL (1 mg/ml) Triclosan (1 mg/ml) Trisonex (1 mg/ml) Vincrinstine Sulfate (1 mg/ml) Vinblastine (1 mg/ml) Vinorelbine (10 mg/ml) Zoledronic Acid (0.8 mg/ml) Carmustine (3.3 mg/ml) permeation occurred at 80.4 minutes	Similar with different breakthrough times for Carmustine.

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 .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 36.80 MPa and after aging of 41.06 MPa and elongation of 748% before aging and 627% after aging.	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 38.6 MPa and after aging of 37.5 MPa and elongation of 702% before aging and 584% after aging.	Similar
ISO 10993 Biological evaluation of medical devices - Tests for Systemic Toxicity	Acceptance criteria: No signs of systemic toxicity up to 72 hours post injection. Result: No systemic toxicity observed.	Acceptance criteria: No signs of systemic toxicity up to 72 hours post injection. Result: No systemic toxicity observed.	Same

ISO 10993 Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization	**Sensitization** Acceptance Criteria: The requirements of the test were met as Grades of less than 1 were observed in the test group and the positive 1-chloro-2,4-dinitrobenzene (DNCB) control preformed as anticipated. Result: The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig (Grade 0). **Irritation** Acceptance Criteria: The requirements of the test were met as Grades of less than 1 were observed. Result: Based on the criteria of the protocol, C2016-0105 Purple Max Powder-Free Exam Glove was considered non-irritating.	**Sensitization** Acceptance Criteria: The requirements of the test were met as Grades of less than 1 were observed in the test group and the positive 1-chloro-2,4-dinitrobenzene (DNCB) control preformed as anticipated. Result: The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig (Grade 0). **Irritation** Acceptance Criteria: The requirements of the test were met as Grades of less than 1 were observed. Result: Based on the criteria of the protocol, C2016-0105 Purple Max Powder-Free Exam Glove was considered non-irritating.	Same

Summary of non-clinical testing	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 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 subject device has a longer cuff and is thicker at the palm.
Conclusion:	Performance data supports 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 K160709.