**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2016

Haylard Health
Gwendolyn George
Regulatory Affairs, Technical Leader
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K160709
Trade/Device Name: HAYLARD* PURPLE NITRILE – XTRA* Powder Free Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC
Dated: August 3, 2016
Received: August 4, 2016

Dear Ms. Gwendolyn George:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160709

Device Name
HALYARD* PURPLE NITRILE - XTRA* Powder Free Exam Gloves

Indications for Use *(Describe)*
HALYARD* PURPLE NITRILE - XTRA* Powder Free Exam Gloves tested for Use with Chemotherapy Drugs are powder-free patient examination gloves that are a disposable device intended for medical purposes worn on the examiner's hand or finger to prevent contamination between patient and examiner. This is an over the counter medical device. The HALYARD* PURPLE NITRILE - XTRA* Powder Free Exam Gloves have been tested with the following Chemotherapy drugs showing no breakthrough up to 240 minutes. Carmustine showed breakthrough at 80.4 minutes

| ChemoTherapy Drug (conc.) | Break-through Time (mins) | ChemoTherapy Drug (conc.) | Break-through Time (mins) | ChemoTherapy Drug (conc) | Break-through Time (mins) |
|---|---|---|---|---|---|
| Arsenic Trioxide (1 mg/ml) | > 240 | Doxorubicin HCl (2 mg/ml) | > 240 | Paraplatin (10 mg/ml) | > 240 |
| Azacitidine (Vidaza) (25 mg/ml) | > 240 | Ellence (2 mg/ml) | > 240 | Pemetrexed (25 mg/ml) | > 240 |
| Bendamustine (5 mg/ml) | > 240 | Eribulin Mesylate (0.5 mg/ml) | > 240 | Pertuzumab (30 mg/ml) | > 240 |
| Bleomycin sulfate (15 mg/ml) | > 240 | Etoposid (20 mg/ml) | > 240 | Raltitrexed (0.5 mg/ml) | > 240 |
| Bortezomib (Velcade) (1 mg/ml) | > 240 | Fludarabine (25 mg/ml) | > 240 | Retrovir (10 mg/ml) | > 240 |
| Busulfan (6 mg/ml) | > 240 | Fulvestrant (50 mg/ml) | > 240 | Rituximab (10 mg/ml) | > 240 |
| Carfilzomib (2 mg/ml) | > 240 | Fluorouracil (50 mg/ml) | > 240 | Temsirolimus (25 mg/ml) | > 240 |
| Carboplatin (10 mg/ml) | > 240 | Gemcitabine (38 mg/ml) | > 240 | ThioTEPA (10 mg/ml) | > 240 |
| **Carmustine (3.3 mg/ml)** | 80.4 | Idarubicin (1 mg/ml) | > 240 | Topotean HCl (1 mg/ml) | > 240 |
| Cetuximab (Erbitux) (2 mg/ml) | > 240 | Ifosfamide (50 mg/ml) | > 240 | Trastuzumab (21 mg/ml) | > 240 |
| Cisplatin (1 mg/ml) | > 240 | Irinotecan (20 mg/ml) | > 240 | Triclosan (1 mg/ml) | > 240 |
| Cyclophosphamide (20 mg/ml) | > 240 | Mechlorethamine HCl (1 mg/ml) | > 240 | Trisenox (0.1 mg/ml) | > 240 |
| Cytarabine HCl (100 mg/ml) | > 240 | Melphalan (5 mg/ml) | > 240 | Vinblastine (1 mg/ml) | > 240 |
| Cytovene (10 mg/ml) | > 240 | Methotrexate (25 mg/ml) | > 240 | Vincristine Sulfate (1 mg/ml) | > 240 |
| Dacarbazine (10 mg/ml) | > 240 | Mitomycin (0.5 mg/ml) | > 240 | Vinorelbine (10 mg/ml) | > 240 |
| Daunorubicin Hcl (5 mg/ml) | > 240 | Mitoxantrone (2 mg/ml) | > 240 | Zoledronic Acid (0.8 mg/ml) | > 240 |
| Decitabine (5 mg/ml) | > 240 | Oxaliplatin (2mg/ml) | > 240 | | |
| Docetaxel (10 mg/ml) | > 240 | Paclitaxel (6 mg/ml) | > 240 | | |

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

| | |
|---|---|
| **Date Summary was Prepared:** | September 6, 2016 |
| **510(k) Submitter:** | Gwendolyn George<br>Technical Leader, Regulatory Affairs<br>Halyard Health<br>5405 Windward Parkway<br>Alpharetta, GA 30004<br>Email: Gwendolyn.George@hyh.com<br>Ph: 520-204-6442<br>Establishment Registration Number 3011270181 |
| **Primary Contact for this 510(k) Submission:** | Gwendolyn George<br>Technical Leader, Regulatory Affairs<br>Halyard Health<br>5405 Windward Parkway<br>Alpharetta, GA 30004<br>Email: Gwendolyn.George@hyh.com<br>Ph: 520-204-6442 |
| **Device Trade Name:** | HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves |
| **Device Common Name:** | Medical Exam Gloves |
| **Device Product Code and Classification Name:** | LZC<br>Class I, 21 CFR §880.6250<br>Patient Examination Glove, Specialty |
| **Predicate Device:** | K113423<br>Kimberly-Clark PURPLE NITRILE –XTRA* Powder-Free Exam Glove tested for use with chemotherapy drugs – 12" Length |
| **Subject Device Description:** | HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves are 12" disposable, purple-colored, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves that have been tested for use with chemotherapy drugs. |
| **Intended Use:** | HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves tested for use with Chemotherapy Drugs are powder-free patient examination gloves that are a disposable device intended for medical purposes worn on the examiner's hand or finger to prevent contamination between patient and examiner. This is an over the counter medical device. The HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves have been tested with the following Chemotherapy drugs showing no breakthrough up to 240 minutes. Carmustine showed break through at 80.4 minutes. |

| ChemoTherapy Drug (conc.) | Break-through Time (mins) | ChemoTherapy Drug (conc.) | Break-through Time (mins) | ChemoTherapy Drug (conc) | Break-through Time (mins) |
|---|---|---|---|---|---|
| Arsenic Trioxide (1 mg/ml) | > 240 | Doxorubicin HCl (2 mg/ml) | > 240 | Paraplatin (10 mg/ml) | > 240 |
| Azacitidine (Vidaza) (25 mg/ml) | > 240 | Ellence (2 mg/ml) | > 240 | Pemetrexed (25 mg/ml) | > 240 |
| Bendamustine (5 mg/ml) | > 240 | Eribulin Mesylate (0.5 mg/ml) | > 240 | Pertuzumab (30 mg/ml) | > 240 |
| Bleomycin sulfate (15 mg/ml) | > 240 | Etoposid (20 mg/ml) | > 240 | Raltitrexed (0.5 mg/ml) | > 240 |
| Bortezomib (Velcade) (1 mg/ml) | > 240 | Fludarabine (25 mg/ml) | > 240 | Retrovir (10 mg/ml) | > 240 |
| Busulfan (6 mg/ml) | > 240 | Fulvestrant (50 mg/ml) | > 240 | Rituximab (10 mg/ml) | > 240 |
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| Carboplatin (10 mg/ml) | > 240 | Gemcitabine (38 mg/ml) | > 240 | ThioTEPA (10 mg/ml) | > 240 |
| **Carmustine (3.3 mg/ml)** | **80.4** | Idarubicin (1 mg/ml) | > 240 | Topotean HCl (1 mg/ml) | > 240 |
| Cetuximab (Erbitux) (2 mg/ml) | > 240 | Ifosfamide (50 mg/ml) | > 240 | Trastuzumab (21 mg/ml) | > 240 |
| Cisplatin (1 mg/ml) | > 240 | Irinotecan (20 mg/ml) | > 240 | Triclosan (1 mg/ml) | > 240 |
| Cyclophosphamide (20 mg/ml) | > 240 | Mechlorethamine HCl (1 mg/ml) | > 240 | Trisenox (0.1 mg/ml) | > 240 |
| Cytarabine HCl (100 mg/ml) | > 240 | Melphalan (5 mg/ml) | > 240 | Vinblastine (1 mg/ml) | > 240 |
| Cytovene (10 mg/ml) | > 240 | Methotrexate (25 mg/ml) | > 240 | Vincrinstine Sulfate (1 mg/ml) | > 240 |
| Dacarbazine (10 mg/ml) | > 240 | Mitomycin (0.5 mg/ml) | > 240 | Vinorelbine (10 mg/ml) | > 240 |
| Daunorubicin Hcl (5 mg/ml) | > 240 | Mitoxantrone (2 mg/ml) | > 240 | Zoledronic Acid (0.8 mg/ml) | > 240 |
| Decitabine (5 mg/ml) | > 240 | Oxaliplatin (2mg/ml) | > 240 | | |
| Docetaxel (10 mg/ml) | > 240 | Paclitaxel (6 mg/ml) | > 240 | | |

(Note within 510(k) Summary only: The difference between the subject and predicate devices' indications for use do not affect substantial equivalence.)

**Summary of Technologies:**

The technological characteristics and intended use of the subject and predicate device are substantially equivalent. The subject device is increased in thickness. This change resulted in improved Carmustine permeation time of 80.4 minutes at a 3.3 mg/ml concentration and expanded chemotherapy drug resistance claim to 23 additional drugs as reflected in the table below.

| F | Subject Device | Predicate Device K113423 | Substantially Equivalent |
|---|---|---|---|
| **FDA Product Code** | LZC | LZC | Yes |
| **FDA Classification** | Class 1 | Class 1 | Yes |
| **Common Name** | Medical Exam Glove | Medical Exam Glove | Yes |
| **Device Trade Name** | HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves | Kimberly-Clark Purple Nitrile-XTRA Powder-Free Exam Gloves – 12" Length | Yes |
| **Intended Use** | HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves are 12" in length, a disposable device intended for medical purposes that is worn on the examiner's hand and finger to prevent contamination between patient and examiner. | The Kimberly-Clark Purple Nitrile-XTRA Powder-Free Exam Glove tested for use with chemotherapy drugs -12" Length is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. | Yes |
| **Technological Characteristics** | Purple colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non - sterile patient examination glove. | Purple colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove. | Yes |
| **Performance Data** | | | |
| ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs | **Acceptance criteria:** No signs of breakthrough after 4 hours. Carmustine showed no signs of breakthrough after 80.4 minutes **Result:** No breakthrough observed. Meets acceptance criteria. **PASS** | **Acceptance criteria:** No signs of breakthrough after 4 hours. Carmustine showed no signs of breakthrough after 30.7 minutes **Result:** No breakthrough observed. Meets acceptance criteria. **PASS** | Yes |
| 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. **PASS** | 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. **PASS** | Yes |
| ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves | Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free. **PASS** | Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free. **PASS** | Yes |

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device<br>K113423</th><th>Substantially Equivalent</th></tr>
<tr><td>Performance Data<br>ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications</td><td>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 and elongation in the standard. Therefore the device meets the acceptance criteria of the standard. PASS<br><table><tr><th>Property</th><th>ASTM</th><th>Halyard Specification</th></tr><tr><td>Holes</td><td>AQL 2.5%</td><td>AQL 1.0%</td></tr><tr><td>Length</td><td>≥230 mm</td><td>295-325 mm</td></tr><tr><td>Width</td><td>85-105mm</td><td>85-105mm</td></tr><tr><td>Finger Thickness</td><td>≥0.05mm</td><td>0.11- 0.19mm</td></tr><tr><td>Palm Thickness</td><td>≥0.05mm</td><td>0.11 -0.16mm</td></tr><tr><td>Unaged Tensile</td><td>≥14 MPa</td><td>≥14 MPa</td></tr><tr><td>Unaged Elongation</td><td>≥500%</td><td>≥500%</td></tr><tr><td>Aged Tensile</td><td>≥14 MPa</td><td>≥14 MPa</td></tr><tr><td>Aged Elongation</td><td>≥400%</td><td>≥500%</td></tr><tr><td>Powder</td><td>≤2mg/glove</td><td>≤2mg/glove</td></tr></table>The Halyard specifications listed above conform to or exceed the ASTM D6319 Standard Specification.</td><td>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 and elongation in the standard. Therefore the device meets the acceptance criteria of the standard. PASS<br><table><tr><th>Property</th><th>ASTM</th><th>Kimberly Clark Specification</th></tr><tr><td>Holes</td><td>AQL 2.5%</td><td>AQL 1.0%</td></tr><tr><td>Length</td><td>≥230 mm</td><td>295 -325 mm</td></tr><tr><td>Width</td><td>85-105mm</td><td>85-105mm</td></tr><tr><td>Finger Thickness</td><td>≥0.05mm</td><td>0.10- 0.19mm</td></tr><tr><td>Palm Thickness</td><td>≥0.05mm</td><td>0.10 -0.16mm</td></tr><tr><td>Unaged Tensile</td><td>≥14 MPa</td><td>≥14 MPa</td></tr><tr><td>Unaged Elongation</td><td>≥500%</td><td>≥500%</td></tr><tr><td>Aged Tensile</td><td>≥14 MPa</td><td>≥14 MPa</td></tr><tr><td>Aged Elongation</td><td>≥400%</td><td>≥500%</td></tr><tr><td>Powder</td><td>≤2mg/glove</td><td>≤2mg/glove</td></tr></table>The Kimberly Clark specifications listed above conform to or exceed the ASTM D6319 Standard Specification.</td><td>Yes</td></tr>
<tr><td>ISO 10993-10 Biological evaluation of medical devices -Tests for Irritation</td><td rowspan="3">Based on an evaluation according to ISO 10993-1, it was determined that no additional testing on the subject glove was needed.</td><td>Acceptance criteria: No erythema/ edema up to 72 hours post exposure.<br>Result: Erythema/edema was negligible. Meets acceptance criteria.<br>PASS</td><td rowspan="3"></td></tr>
<tr><td>ISO 10993-10 Biological evaluation of medical devices - Tests for Skin Sensitization</td><td>Acceptance criteria: No evidence of delayed dermal contact sensitivity at 24 and 48 hours post injection.<br>Result: Not a sensitizer under conditions of the study. Meets acceptance criteria. PASS</td></tr>
<tr><td>ISO 10993-11 Biological evaluation of medical devices - Tests for Systemic Toxicity</td><td>Acceptance criteria: No signs of systemic toxicity up to 72 hours post injection.<br>Result: No systemic toxicity observed. Meets acceptance criteria.<br>PASS</td></tr>
<tr><td>Conclusion</td><td colspan="3">The 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 K113423.</td></tr>
</table>

The HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves were tested for use with the following drug concentrations per ASTM D6978-05. All study results were acceptable.

***The following drugs had NO breakthrough detected up to 240 minutes:***

| Additional Chemotherapeutic Drugs tested | Drug Concentration |
|---|---|
| Arsenic Trioxide | 1 mg/ml |
| Azacitidine (Vidaza) | 25 mg/ml |
| Bendamustine | 5 mg/ml |
| Bortezomib (Velcade) | 1 mg/ml |
| Carfilzomib | 2 mg/ml |
| Cetuximab (Erbitux) | 2 mg/ml |
| Cytovene | 10 mg/ml |
| Decitabine | 5 mg/ml |
| Eribulin Mesylate | 0.5 mg/ml |
| Fulvestrant | 50 mg/ml |
| Oxaliplatin | 2mg/ml |
| Paraplatin | 10 mg/ml |
| Pemetrexed | 25 mg/ml |
| Pertuzumab | 30 mg/ml |
| Raltitrexed | 0.5 mg/ml |
| Retrovir | 10 mg/ml |
| Temsirolimus | 25 mg/ml |
| Topotean HCl | 1 mg/ml |
| Trastuzumab | 21 mg/ml |
| Triclosan | 1 mg/ml |
| Vinblastine | 1 mg/ml |
| Vinorelbine | 10 mg/ml |
| Zoledronic Acid | 0.8 mg/ml |
| | |
| | |
| | |
| | |
| | |

| Chemotherapeutic Drugs Listed on Predicate labeling | Drug Concentration |
|---|---|
| Bleomycin sulfate | 15 mg/ml |
| Busulfan | 6 mg/ml |
| Carboplatin | 10 mg/ml |
| Cisplatin | 1 mg/ml |
| Cyclophosphamide | 20 mg/ml |
| Cytarabine HCl | 100 mg/ml |
| Dacarbazine | 10 mg/ml |
| Daunorubicin Hcl | 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 |
| 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 |
| Paclitaxel | 6 mg/ml |
| Rituximab | 10 mg/ml |
| ThioTEPA | 10 mg/ml |
| Trisenox | 0.1 mg/ml |
| Vincrinstine Sulfate | 1 mg/ml |

**Carmustine was retested on the subject device with breakthrough detected in 80.4 minutes at a concentration of 3.3 mg/ml. The predicate device had breakthrough detected at 30.7 minutes.**

| | |
|---|---|
| **Technological Characteristics and Substantial Equivalence:** | The HALYARD* PURPLE NITRILE – XTRA* Powder-Free Exam Gloves is substantially equivalent to the predicate device, Kimberly-Clark Purple Nitrile-XTRA Powder-Free Exam Gloves tested for use with chemotherapy drugs (K113423). We are submitting this 510(k) for clearance of expanded chemotherapy drug claim on the product labeling based on testing in accordance with ASTM D6978-05 for chemical permeation to twenty three (23) additional chemotherapy drugs with improved permeation to Carmustine. The test results demonstrate no new issues of safety and efficacy. |
| **Summary of Testing:** | These gloves have been tested for conformance to the applicable sections of the following standards:<br><br>ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs<br><br>ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves<br><br>ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications<br><br>ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves<br><br>ALL RESULTS OF TESTING MET ACCEPTANCE CRITERIA. |
| **Brief Description of Clinical Tests:** | No new clinical tests were required to support this 510(k) notification. |
| **Conclusion:** | The 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 K113423. |