September 3, 2020

ATTWILL Medical Solutions
Amarinder S. Gill
Director of Quality
925 Development Drive
Lodi, Wisconsin 53555

Re: K200641
Trade/Device Name: HaloGUARD Protective Disc with CHG
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 4, 2020
Received: June 5, 2020

Dear Amarinder S. Gill:

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,

Anjana Jain, Ph.D.
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)*
K200641

Device Name
HaloGUARD™ Protective Disc with CHG

Indications for Use *(Describe)*
HaloGUARD™ Protective Disc with CHG is intended to cover insertion sites on adult patients. Common applications include IV catheters, central venous lines, epidural catheters, PICCs, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices.

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

1 Submitter

ATTWILL Medical Solutions
925 Development Drive
Lodi, WI 53555
Phone: 608-592-6925

Amarinder S. Gill
Director of Quality
Email: sgill@attwillmedical.com

Preparation Date: September 3, 2020

2 Regulatory Information

Device Name: HaloGUARD™ Protective Disc with CHG
Common Name: Dressing, Wound, Drug
FDA Panel: General and plastic surgery
Product Code: FRO
Class: Unclassified

3 Predicate Device

K003229 – BIOPATCH Protective Disk with CHG

4 Device Description

HaloGUARD™ Protective Disc with CHG is a sterile, single use disposable disc infused with the antibacterial agent chlorhexidine gluconate (CHG). The average CHG concentration per disc is outlined in **Table 1**.

Table 1. Average Cocentration per Disc

AVERAGE CONCENTRATION PER DISC		
Model Number	**Description**	**CHG Amount (mg)**
HG0141	1 in disc, 4 mm hole	90
HG0171	1 in disc, 7 mm hole	85
HG0075151	0.75 in disc, 1.5 mm hole	51

5 Indications for Use

HaloGUARD™ Protective Disc with CHG is intended to cover insertion sites on adult patients. Common applications include IV catheters, central venous lines, epidural catheters, PICCs, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices.

6 Substantial Equivalence Discussion

The review of the indications for use and comparison characteristics provided in **Table 2** demonstrate that HaloGUARD™ Protective Disc with CHG is substantially equivalent to the predicate device, BIOPATCH Protective Disk with CHG.

Table 2. Summary Comparison of Characteristics

Characteristic	Subject Device HaloGUARD™ Protective Disc with CHG K200641	Predicate Device BIOPATCH Protective Disk with CHG K003229
FDA Product Code	FRO	FRO
Indications for Use	HaloGUARD™ Protective Disc with CHG is intended to cover insertion sites on adult patients. Common applications include IV catheters, central venous lines, epidural catheters, PICCs, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices.	BIOPATCH containing Chlorhexidine Gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, peripherally inserted coronary catheters, mid-line catheters, drains, chest tubes, externally placed orthopedic pins, and epidural catheters. It is also intended to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.
Single Use	Yes	Yes
Disposable	Yes	Yes
Material	Medical grade foam impregnated with CHG with a film backing with print	Medical grade foam impregnated with CHG with a film backing with print
Antibacterial Agent	Chlorhexidine gluconate (CHG)	Chlorhexidine gluconate (CHG)
Sterilization Method	E-beam Radiation	Ethylene Oxide
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}

Characteristic	Subject Device HaloGUARD™ Protective Disc with CHG K200641	Predicate Device BIOPATCH Protective Disk with CHG K003229
Shelf Life	Six (6) months	Two (2) years
Biocompatible	Yes	Yes

7 Sterilization and Shelf Life

The subject device will be provided sterile via E-beam sterilization at a dose of 35 kGy. The shelf life for HaloGUARD™ Protective Disc with CHG is up to and no more than 6 months. The sterility tests of HaloGUARD™ Protective Disc with CHG have been proferomed on representative finished, sterilized devices as follow:

- Bacterial Endotoxin – USP <85>, FDA Recognized Standard 2-522 and USP <161>, FDA Recognized Standard 2-523
- Bioburden – USP <51>

8 Biocompatibility

The results from the biocompatibility testing demonstrate that HaloGUARD™ Protective Disc with CHG is safe and effective, and substantially equivalent to the predicate device Biopatch for its intended use. The HaloGUARD™ Protective Disc with CHG indicated for prolonged contact with breached or compromised surfaces for > 24 hours and up to 30 days. Biocompatibility endpoints evaluated for HaloGUARD™ Protective Disc with CHG have been performed on representative finished, sterilized devices include:

- Cytotoxicity – ISO 10993-5 Tests for In Vitro Cytotoxicity, FDA Recognized Standard 2-245
- Irritation – ISO 10993-10 Tests for Irritation and Skin Sensitization, FDA Recognized Standard 2-174
- Material-Mediated Pyrogenicity – ISO 10993-11 Tests for Systemic Toxicity, FDA Recognized Standard 2-255
- Sensitization – ISO 10993-10 Tests for Irritation and Skin Sensitization, FDA Recognized Standard 2-174
- Subacute Systemic Toxicity – ISO 10993-11 Tests for Systemic Toxicity, FDA Recognized Standard 2-255

9 Performance Testing - Bench

The results from the performance bench testing demonstrate that HaloGUARD™ Protective Disc with CHG has met the functional requirements and is substantially equivalent to the predicate device. Performance bench tests of HaloGUARD™ Protective Disc with CHG have been performed on representative finished, sterilized devices as follows:

- Absorbency Factor – Internal test method
- Antimicrobial Efficacy (4 log reduction and 7 day study) – USP <51>
- Appearance – Internal test method
- CHG Concentration Determination – Internal test method

10 Animal Studies

The results from the animal study demonstrate that HaloGUARD™ Protective Disc with CHG does not delay the natural wound healing response. The animal study of HaloGUARD™ Protective Disc with CHG has been performed on representative finished, sterilized devices as follows:

- Wound Healing – ISO 10993-6 Tests for Local Effects After Implantation, FDA Recognized Standard 2-247

11 Clinical Testing

Clinical testing was not required to support substantial equivalence.

12 Conclusion

The subject device HaloGUARD™ Protective Disc with CHG is substantially equivalent to the predicate device. HaloGUARD™ Protective Disc with CHG shares a substantially equivalent design, indications for use and technology (i.e. features, materials, and principles of operation) with the predicate device and no new questions of to safety or effectiveness have been identified.