December 9, 2024

Hartmann USA, Inc.
% Lorry Weaver
Principal Consultant, Regulatory Affairs
Qserve Group US
350 S. Main Street
Doyelstown, Pennsylvania 18901

Re: K242758
Trade/Device Name: Atrauman® Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 12, 2024
Received: September 12, 2024

Dear Lorry Weaver:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242758

Device Name
Atrauman® Ag

Indications for Use *(Describe)*
Atrauman® Ag antimicrobial wound dressing is indicated for use with moderately exuding wounds such as pressure wounds, venous leg ulcers, diabetic ulcers, partial thickness burns, Skin graft donor sites, surgical graft donor sites, surgical wounds, and abrasions.

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.

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510(k) Summary – [21 CFR 807.92]

807.92(a)(1), (2), (3)

Date Prepared: November 22, 2024

Submitter's Name: Hartmann USA
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803-325-7600

Official Correspondent: Lorry Weaver, Principal Consultant
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Device Trade Name: Atrauman® Ag

Common Name: Antimicrobial wound dressing with silver

Review Panel: General & Plastic Surgery (OHT4)

Classification Name: Unclassified

Regulation No.: Unclassified

Classification Code: FRO

Predicate Device: Urgotul Ag: 510(k) Number K100430
Product Code: FRO
Regulation: Unclassified

Device Description Summary *807.92(a)(4)*:

Atrauman® Ag antibacterial solid wound dressing is a non-adherent silver impregnated antibacterial dressing that provides a moist wound environment. The dressing is composed of a meshed hydrophobic polyamide textile coated with metallic silver (2.1 mg/sq inch) that kills bacteria within the dressing and a hydrophilic matrix consisting mainly of triglycerides. The mesh fabric allows silver ion formation on its surface upon contact with exudate. The wound dressing is non-adhesive for dressing changes and can be cut-to-size.

Intended Use/Indications for Use *807.92(a)(5)*:

Atrauman® Ag antimicrobial wound dressing is indicated for use with moderately exuding wounds such as pressure wounds, venous leg ulcers, diabetic ulcers, partial thickness burns, skin graft donor sites, surgical graft donor sites, surgical wounds, and abrasions.

Technological Comparison *807.92(a)(6)***:**

Atrauman Ag and the predicate device, UrgoTul Ag/Silver have similar indications for use and technological characteristics. Functionally, both devices have a non-adherent contact (hydrophobic polyamide mesh) layer and; both devices include silver for its antibacterial properties within the dressing and both devices have an impregnated hydrophilic matrix that contributes to maintaining a moist environment and exudate absorption. Finally, both devices are suitable for wounds such as moderately exudative partial and full thickness wounds, including diabetic ulcers, first and second degree burns, decubitus ulcer, venous statis ulcer. The antibacterial activity may inhibit growth of bacteria within the dressing up to 7 days.
The contact layer of both devices is non-adhesive, non-occlusive, have a matrix design with hydrophilic material. The hydrophilic material provides a moist environment including the wound edges.

Differences between the devices do not raise new and/or different questions of safety and effectiveness. Differences include the UrgoTul Ag/Silver additionally can be used on graft and donor sites while the Atrauman Ag currently does not have data to support that wound type.

Atrauman Ag fibers of the support fabric are coated with elemental silver whereas UrgoTul Ag/Silver uses silver sulfate in the matrix applied to the polyamide mesh along with other ingredients.

Summary of Non-Clinical Test – Performance and Safety Testing *807.92(b)(1)***:**

Atrauman Ag was evaluated and found to meet standards and requirements for biocompatibility, antimicrobial effectiveness, sterilization, shelf-life, and packaging.

Biocompatibility

Biocompatibility testing was conducted on the device according to ISO 10993-1 for prolonged exposure (> 24 hours to 30 days), surface device, breached or compromised surface. Cytotoxicity, sensitization, irritation or intracutaneous reactivity, material mediated pyrogenicity.

The following standards were used:

Biological Endpoint	**Standard**
Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2021
Irritation or intracutaneous reactivity	ISO 10993-23:2021
Material mediated pyrogenicity	ISO 10993-11:2017
Acute, subacute, subchronic systemic toxicity	ISO 10993-11:2017
Implantation effects	ISO 10993-6: 2016

Antimicrobial Effectiveness

Atrauman Ag wound dressing samples were tested under simulated use conditions with six clinically relevant microorganisms. Results demonstrated that the wound dressings are effective up to 7 days throughout the labeled shelf-life indicating that the antibacterial agent (silver) may help inhibit the growth of bacteria within the dressing.

Sterilization

Atrauman Ag wound dressings are terminally sterilized via gamma irradiation and the method validated with an SAL of 10^{-6}. The sterilization validation was performed and is monitored according to the following standards:

Standard number	Title
EN 556-1:2001/AC:2006	Sterilization of medical devices –Requirements for medical devices to be designated "STERILE" –Part 1: Requirements for terminally sterilized medical devices
EN ISO 11137-1:2015 + A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11737-1:2018 + A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ANSI/AAMI ST72:2019	Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing

Packaging and Shelf-life

Atrauman Ag is labeled with a 3 year shelf-life according to real-time testing demonstrating full product performance after 3 years aging. Transport testing was performed according to ASTM D4169 and met acceptance criteria.

Summary of Clinical Tests *807.92(b)(1)*:
Not applicable

Conclusions *807.92(b)(1)*:
Atrauman® Ag and UrgoTul™ Ag are both product code FRO that is an unclassified regulation. The differences between the devices do not raise new and/or different questions of safety and effectiveness. Atrauman® Ag conforms to applicable safety standards and performance data validates the intended use. The predicate comparison table and performance testing provided in this 510(k) is sufficient to demonstrate that the Atrauman® Ag is substantially equivalent to the legally marketed predicate device, UrgoTul™ Ag cleared under 510(k) K100430.