February 6, 2026

Amferia AB
% David Cox
Regulatory consultant
GR Consulting
14 N. Main St.
Cranbury, New Jersey 08512

Re: DEN250006
Trade/Device Name: Amferia Wound Dressing
Regulation Number: 21 CFR 878.4013
Regulation Name: Solid wound dressing with permanently bound antimicrobial agent
Regulatory Class: Class II
Product Code: SHA
Dated: March 3, 2025
Received: March 3, 2025

Dear David Cox:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Amferia Wound Dressing, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Amferia Wound Dressing is intended to cover and protect dry-to-low exuding wounds (e.g. abrasions, skin tears, lacerations, incisions and surgical wounds, superficial and partial-thickness burns, pressure ulcers, arterial ulcers), and to maintain an appropriate moisture balance within the wound.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Amferia Wound Dressing, and substantially equivalent devices of this generic type, into Class II under the generic name solid wound dressing with permanently bound antimicrobial agent.

FDA identifies this generic type of device as:

> **Solid wound dressing with permanently bound antimicrobial agent.** A solid wound dressing with permanently bound antimicrobial agent consists of a solid wound dressing containing antimicrobial permanently bound to the substrate surface. The solid wound dressing is used to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound and is

intended for use only on external cutaneous (skin) wounds. The solid wound dressing is provided sterile in a form able to hold structural integrity. Antimicrobials are used for protectant purposes only to reduce microbial growth within the solid wound dressing while in use, or to provide an antimicrobial barrier to microbial penetration through the solid wound dressing. This classification does not include solid wound dressings containing a medically important antimicrobial as defined in special control (1).

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 3, 2025, FDA received your De Novo requesting classification of the Amferia Wound Dressing. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Amferia Wound Dressing into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Amferia Wound Dressing can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Performance testing and technological characteristics Biocompatibility evaluation Antimicrobial leachability testing Labeling
Toxicity	Performance testing and technological characteristics Biocompatibility evaluation Antimicrobial leachability testing Labeling
Delayed wound healing	Performance testing and technological characteristics Biocompatibility evaluation Antimicrobial leachability testing Labeling
Incompatibilities with other therapies	Labeling
Contribution to the spread of antimicrobial resistance (AMR)	Exclusion of medically important antimicrobials Antimicrobial characterization and performance testing

	Antimicrobial leachability testing AMR risk assessment Labeling
Infection	Antimicrobial characterization and performance testing Shelf life validation Sterilization validation Labeling
Microbial growth within the product during use	Antimicrobial characterization and performance testing Antimicrobial leachability testing Sterilization validation
Product degradation during stated shelf storage	Shelf life validation Labeling
Retention of dressing material in wound	Performance testing and technological characteristics Labeling
Loss of barrier function	Antimicrobial characterization and performance testing

In combination with the general controls of the FD&C Act, the wound dressing with permanently bound antimicrobial agent is subject to the following special controls:

(1) The device must not contain antimicrobials considered by FDA to be medically important. Medically important antimicrobials are antimicrobials that are important for therapeutic use in humans and associated with a high level of antimicrobial resistance concern (AMR). Medically important antimicrobials include the following classes: Allylamines, Aminocyclitols, Aminoglycosides, Aminomethylcyclines, Amphenicols, Antifolates, Ansamycins, Azoles, Beta-lactams both with and without Beta-lactamase inhibitors, Carbapenems, Cephalosporins, Cephamycins, Cyclic Polypeptides, Dihydrofolate Reductase Inhibitors, Echinocandins, Fluorocyclines, Fluoroquinolones, Fosfomycins, Fusidanes, Glycopeptides, Glycylcyclines, Heterocyclic compounds, Hydroquinolones, Lincosamides, Lipoglycopeptides, Lipopeptides, Macrolides and Ketolides, Macrocyclic peptides, Monobactams, Nitrofurans, Nitroimidazoles, Oxazolidinones, Penems, Penicillins, Phosphonic Acid Derivatives, Pleuromutilins, Polyenes, Polymyxins, Pseudomonic acids, Quinolones, Rifampin, Riminofenazines, Streptogramins, Sulfonamides, Sulfones, or Tetracyclines.

(2) Performance testing and technological characteristics must demonstrate the functionality of the device to achieve the intended use, including:
   (i) The physical and chemical characteristics of the solid wound dressing must be established. The following must be provided:
      (A) Identity, quantification, and purpose of each component in the finished product;
      (B) Description of the process by which the antimicrobial is bound to the substrate, including the resulting type of bonding (e.g. covalent, ionic, etc.);
      (C) Specifications and characterization of each component in the finished product; and
      (D) Final release specifications for the manufactured solid wound dressing.
   (ii) Performance data must demonstrate that components are present in appropriate amounts to perform as intended under anticipated conditions of use, including evaluation of expected worst-case conditions.

(iii) The device must be demonstrated to be sterile.
(iv) The device must be demonstrated to be biocompatible.
(v) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including evaluation of expected worst-case conditions.
(vi) Performance data must support the shelf life of the device by demonstrating package integrity and product functionality over the identified shelf life.

(3) Antimicrobial characterization and performance testing must address the following:
(i) The technological characteristics of the device must indicate the purpose of the antimicrobial and performance data must demonstrate it is present in appropriate amounts to perform as intended under anticipated conditions of use and storage conditions. If the antimicrobial is present as a microbial barrier to cover and protect a wound, microbial barrier testing must demonstrate elimination of passage of microorganisms through the solid wound dressing. If the antimicrobial is present to inhibit microbial growth within the solid wound dressing being used to cover and protect a wound, antimicrobial effectiveness testing must demonstrate inhibition of microbial growth within the solid wound dressing during use. This testing must include:
(A) Establishment of the Minimum Effective Concentration (MEC) of the antimicrobial in the context of the final solid wound dressing;
(B) Identification of the period of effectiveness (i.e., maximum product use life) based on concentration of antimicrobial, leachability data, and performance under expected worst-case simulated use conditions; and
(C) For the tests conducted, evaluation with clinically relevant microbial species, including available strains of challenge organisms containing specific antimicrobial resistance mechanisms as part of expected worst-case scenario performance testing.
(ii) Performance test data must demonstrate that the antimicrobial is bound to the dressing substrate and does not leach from the dressing. This testing must include:
(A) Extraction studies exposing the dressing to justified conditions to evaluate the leachability of the antimicrobial (e.g. prolonged extraction in solvents of different polarity at elevated temperatures); and
(B) Assessment of the potential for substrate and/or coating degradation leading to leaching of the antimicrobial.
(iii) Evaluation and identification, based on literature review, of any probable risks for probable contributions to the development and spread of antimicrobial resistance (AMR) must be provided, and must include:
(A) Identification of the antimicrobial, proposed mechanism(s) of action, and expected spectrum of activity; and
(B) An AMR assessment for each antimicrobial, including the following characterization elements based on literature review:
(1) Known resistance mechanisms;
(2) Transmissibility of resistance mechanisms;
(3) List of resistant microbial species; and
(4) Potential for coselection (e.g., via coresistance or cross-resistance) for medically important antimicrobial resistance mechanisms.

(4) Any statements in labeling must be clear such that they may be understood by the end user, supported by appropriate evidence, and consistent with the intended use of covering and protecting a wound, absorbing exudate, and maintaining appropriate moisture balance within the wound. The labeling must include:
   (i) Instructions regarding the proper placement, sizing, duration of use for the solid wound dressing, frequency of use, and removal of the solid wound dressing, if applicable;
   (ii) A list of each ingredient or component within the solid wound dressing;
   (iii) A warning statement regarding any known incompatibilities with other potential therapies;
   (iv) Instructions to monitor for signs of infection;
   (v) A statement regarding the potential retention of material in the wound or the surrounding area and any applicable instructions for removal of this material;
   (vi) A contraindication for any known sensitivity to components within the product;
   (vii) A shelf life (i.e., maximum period the unopened solid wound dressing is stable while stored on the shelf under a specified range of environmental conditions);
   (viii) A maximum use life per application of solid wound dressing (i.e., period the solid wound dressing is recommended for use prior to removal);
   (ix) A statement regarding when to discontinue use of the solid wound dressing after multiple reapplications based on biocompatibility and performance testing;
   (x) A statement of the role of the antimicrobial in the device. All statements regarding the antimicrobial must be consistent with and placed in the context of the role as a protectant;
   (xi) A warning statement regarding the potential for selection of antibiotic resistant organisms if the wound dressing contains an antimicrobial that may indirectly select for organisms with medically important antimicrobial resistance mechanisms; and
   (xii) A statement that the antimicrobial is not intended to affect wound bioburden.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the solid wound dressing with permanently bound antimicrobial agent they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Scott Herting at 240-402-6148.

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Acting Director
DHT4B: Division of Plastic and
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