April 7, 2023

Advamedica Inc.
℅ Alan Donald
President
Matrix Medical Consulting, Inc.
8880 Rio San Diego Drive,
Suite 800
San Diego, California 92108

Re: K222909
Trade/Device Name: Axiostat Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 2, 2023
Received: March 2, 2023

Dear Alan Donald:

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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
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)*

K222909

Device Name
Axiostat Gauze

Indications for Use *(Describe)*

Prescription:
The Axiostat Gauze is intended for use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.

Over-the-Counter:
The Axiostat Gauze is indicated for the local management of bleeding wounds such as minor cuts, lacerations, 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.

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510(k) SUMMARY

AXIOSTAT GAUZE

1. ADMINISTRATIVE INFORMATION

a. Date of preparation: 4/7/2023

b. Submitter: Advamedica Inc.
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c. Contact Person: Mr. Leo Mavely,
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d. Prepared By: Mr. Leo Mavely, President
Advamedica, Inc.

2. DEVICE NAME AND CLASSIFICATION

a. Trade/ Proprietary Name	:	Axiostat Gauze
b. Common Name	:	Wound dressing
c. Classification Name	:	Dressing, Wound, Drug
d. Regulatory Class	:	Unclassified
e. Product code	:	FRO
f. Classification Panel	:	General and Plastic Surgery

3. IDENTIFICATION OF PREDICATE DEVICE

Table. 1: Predicate Device Details

Parameters	Predicate Device	Proposed Device
510(k) Number	K143462	K222909
Trade/Proprietary Name	Anscare ChitoClot Gauze	Axiostat Gauze
Manufacturer	BenQ Materials Corporation	Advamedica Inc.
Regulatory Class	Unclassified	Unclassified
Classification Name	Dressing, Wound, Drug	Dressing, Wound, Drug
Product Code	FRO	FRO
Panel	General & Plastic Surgery	General & Plastic Surgery

4. DEVICE DESCRIPTION

The Axiostat Gauze is a single-use, non-absorbable non-woven hemostatic gauze. It is made of non-woven fabric derived from chitosan, which is a naturalpolymer. Chitosan is known for its mucoadhesiveand hemostatic properties.

When applied directly to a wound the dressing controls bleeding and can be removed after the clotting has occurred. The dressing should be removed within 24 hours. The dressing is not intended to be implanted.

The Axiostat Gauze is individually packed in a moisture proof packaging and terminally sterilized by gamma radiation to a sterility assurance level (SAL) of 10^{-6}.

Fig 1: Axiostat Gauze

The Axiostat Gauze can be cut to any size within the permissible size limit and packed in three different folds,

a) Folded gauze in the form of single ply, 2-ply, or 4-ply folds,
b) Z-folded gauze in the form of zig-zag pattern
c) Rolled gauze in the form of a roll.

Axiostat Gauze is currently available in the following sizes.

Folded single ply, 2 ply, 4 ply
2”x2” (5 cm x 5cm)
3”x3” (7.5cmx 7.5cm)
4”x4” (10cm x10cm)
6”x6” (15cm x15cm)
8”x8” (20cm x 20cm)
12”x12” (30cm x30cm)
16”x16” (40cm x 40cm)

Z folded
3” x 59” (7.6cm x 150cm)
3” x 78” (7.6cm x 200cm)
3” x 98” (7.6cm x 250cm)

3" x 118" (7.6cm x 300cm)

3" x 137" (7.6cm x 350 cm)

3" x 156" (7.6cm x 400cm)

Rolled

3" x 19" (7.6cm x 50cm)

3"x 39" (7.6cm x 100cm)

3" x 59" (7.6cm x 150cm)

3" x 78" (7.6cm x 200cm)

3" x 98" (7.6cm x 250cm)

3" x 118" (7.6cm x 300cm)

5. INDICATIONS FOR USE

5.1 Prescription Use:

The Axiostat Gauze is intended for use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.

5.2 Over the Counter Use:

The Axiostat Gauze is indicated for the local management of bleeding wounds such as minor cuts, lacerations, and abrasions.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF SUBJECT AND PREDICATE DEVICES

The Axiostat Gauze is technologically similar to Anscare ChitoClot Gauze. The subject device has the following similarities to the predicate device:

- Indication for use
- Mechanism of action
- Active material
- Sterility
- Biocompatibility
- Packaging
- Contact duration and anatomical site

Table 2: Comparison of technological characteristics of the Predicate Device and Subject Device

Parameters	Predicate Device	Subject Device	Notes
510(k) Number	K143462	K222909	--
Trade/Proprietary Name	Anscare ChitoClot Gauze	Axiostat Gauze	--
Manufacturer	BenQ Materials Corporation	Advamedica Inc.	--
Regulatory Class	Unclassified	Unclassified	Same
Product Code	FRO	FRO	Same
Indication for use (prescription use)	For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.	The Axiostat Gauze is intended for use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.	Same
Indication for use (OTC)	To control bleeding of lacerations, minor cuts, and abrasions.	To control bleeding of lacerations, cuts, and abrasions.	Same
Anatomical Site	External Wounds	External Wounds	Same
Physical composition	Soft absorbent, non-woven gauze	Soft absorbent, non-woven gauze	Same

Material	Chitosan	Chitosan	Same
Indicated for control of bleeding?	Yes	Yes	Same
Contact Duration	Up to 24 hours	Up to 24 hours	Same
Mechanism of Action	When applied directly on a wound with firm pressure, the AnsCare ChitoClot Gauze will turn into a gel-like condition to absorb the blood and seal the wound.	When applied on the bleeding site with firm pressure, the Axiostat Gauze acts as a mechanical barrier against bleeding.	Similar
Shelf life	36 months	30 months	Similar
Biocompatibility (ISO 10993)	Yes	Yes	Same
Sterility	Gamma-Sterilized	Gamma-Sterilized	Same
Packaging	Foil-Pouch	Foil-Pouch	Same
Sizes	Various	Various	Same

7. PERFORMANCE DATA

The Subject Device has been evaluated through a series of nonclinical studies to determine whether Axiostat Gauze meets the acceptance criteria for its intended applications. These tests are summarized below.

7.1. Biocompatibility testing

The Biocompatibility tests have been performed as per the requirements of ISO 10993-1:2009, under the section "Surface devices used on Breached or compromised surface" with limited contact duration (≤ 24 hrs)"

The following tests have been carried out as per these requirements-

Table 3: Biocompatibility test details

S.No.	Biocompatibility test	Standard followed	Outcome
1.	Cytotoxicity	ISO 10993-5	Non-cytotoxic
2.	Skin Sensitization	ISO 10993-10	Non-toxic
3.	Acute Dermal Irritation	ISO 10993-10	Non-toxic
4.	Acute Systemic Toxicity	ISO 10993-11	Non-toxic
5.	Hemolysis	ISO 10993-4	Non-hemolytic
6.	Bacterial Endotoxin Test	USP 161	Complies

7.2. Heavy metal testing

The Subject Device was tested for the heavy metal contamination in the finished sterilized product, which met USP-232 limits ((232) ELEMENTAL IMPURITIES—LIMITS).

7.3. Residual solvent testing

The subject device was tested for the presence of residual solvents - isopropyl alcohol (IPA) and acetic acid in the device as per USP 30 <467>. This test is intended to assess the performance and safety of the device. It was found that the Axiostat Gauze is entirely composed of chitosan acetate and the level of residual isopropyl alcohol and acetic acid in the Axiostat Gauze are within the safety limit.

7.4. Bench performance testing

The Subject Device is evaluated through following bench tests.

Table 4: Bench performance testing

S.No	Test	Acceptance Criteria	Reference/Justification
1.	Appearance	**Color -** Cream/off yellow **Foreign particle/undesired physical appearances** No loose fibers, no holes/tears, no dust particles	The product is visually checked before packing to ensure it meets the set criteria.
2.	Moisture content	Not more than 35% in the test device	Moisture from the manufacturing process may be retained in the finished product. Moisture content results in the stability study are less than 35% at all time points, with no change in the desired properties.
3.	Absorbency	Not less than 15 times of product weight	Traditional laparotomy sponges absorb 5 times their weight in fluid. Axiostat Gauze is an advanced hemostat that absorbs fluids up to 15 times its own weight.
4.	pH	5 to 7	A mildly acidic to neutral pH is required for adhesion and hemostatic activity.
5.	Tensile strength	Dry - >5N/25mm Wet - >1N/25mm	The adhesive strength to the tissue/application site is less than the set acceptance criteria for Tensile strength. This prevents the product from breaking during removal from the application site.

6.	Integrity (dispersion test)	Product remain intact	The outcome demonstrates the integrity of Axiostat Gauze on the application site. BS EN 13726-1:2002
7.	In-vitro clot assessment	**Blood clotting time:** Clotting time with Axiostat Gauze should be not more than 60% average clotting of control (recalcified blood) **Blood clotting index:** The BCI of Axiostat Gauze should be not more than 5% Blood clotting Index	**Blood clotting time:** The faster the blood clots compared to recalcified blood (control), the better the hemostatic efficacy of Axiostat Gauze. **Blood clotting index:** represents the percentage of non-coagulated blood in the Axiostat Gauze, and the lower the BCI, the better the clotting.

7.5. Animal studies

Animal testing was conducted to evaluate the hemostatic efficiency of the Axiostat Gauze in extremity arterial hemorrhage model in swine at an external laboratory as necessitated by FDA standards.

Advamedica has performed the animal testing as described in-

"Safety Evaluation of New Hemostatic Agents, Smectite Granules, and Kaolin-Coated Gauze in a Vascular Injury Wound Model in Swine; Kheirabadi, et al., J Trauma. 2010 Feb;68(2):269-78."

The Subject Device successfully achieved hemostasis in under 5 minutes in all test animals and no rebleeding was observed in any animals during the observation period of two hours.

8. Sterilization and Shelf life

The Axiostat Gauze is packaged in moisture proof packs. The product is terminally sterilized using gamma radiation to a sterility assurance level (SAL) of 10^{-6}. The dose of gamma radiation has been optimized and validated per ISO 11137-2.

Following gamma sterilization, the package integrity was subjected to sterile barrier testing to validate a shelf life of 30 months. The stability and effectiveness of packaging of the sterilized product during the shelf-life was confirmed by real time (to support 30 months shelf life) and accelerated stability studies.

The following tests were performed periodically in the validation of 30 months shelf life.

Product tests to validate the shelf life are as mentioned below -

- Appearance - visual check
- Moisture content as per ASTM E1868-10
- Absorbency as per BS EN 13726-1:2002
- pH as per BS EN 13726-1:2002
- Dispersion or integrity test as per BS EN 13726-1:2002
- Tensile strength test as per BS EN 29073-3:1992 and ISO 9073-18

Package tests to validate the shelf life are as mentioned below -

- Seal strength test as per ASTM F88
- Dye penetration test as per ASTM F3039-15
- Sterility test as per US Pharmacopeia <71>
- Bacterial Endotoxin Test as per US Pharmacopeia <161>

9. Conclusion

The Axiostat Gauze is substantially equivalent to the predicate device with respect to the risk-based classification, product code as defined by US FDA, intended use & indications for use, application site, physical composition, design material, method of sterilization, and biocompatibility. The non-clinical testing data provided supports the safety and performance of the device for the claimed Indications for Use statement. Hence, the minor differences between the subject devices and the predicates do not raise any new device safety or performance issues.