February 23, 2018

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

Re: K172324
Trade/Device Name: Axiostat Chitosan Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 22, 2018
Received: January 23, 2018

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K172324

Device Name
Axiostat Chitosan Hemostatic Dressing

Indications for Use *(Describe)*
Axiostat Chitosan Hemostatic Dressing is indicated to control bleeding of lacerations, minor cuts 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

**510(k) SUMMARY – K172324**

Advamedica, Inc.

AXIOSTAT CHITOSAN HEMOSTATIC DRESSING

**ADMINISTRATIVE INFORMATION**

**a. Date of Preparation:** February 23, 2018

**b. Submitter:**
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**c. Official Contact:**
Mr. Leo Mavely, President
Email: office@advamedica.com
Web: www.advamedica.com

**d. Prepared By:**
Mr. Leo Mavely, President
Advamedica, Inc.

## 2. DEVICE NAME AND CLASSIFICATION

**a. Trade/Proprietary Names:** Axiostat Chitosan Hemostatic Dressing

**b. Common Name:** Hemostatic Dressing

**c. Classification Name:** Dressing, Wound, Drug

**d. Device Class:** Unclassified

**e. Product Codes:** FRO

**f. Classification Panel:** General and Plastic Surgery

## 3. PREDICATE DEVICE

| | |
|---|---|
| **Proprietary/Trade name** | Chito-SAM™ Active |
| **Manufacturer** | SAM Medical Products |
| **Classification Name** | Dressing, Wound, Drug |
| **Device Class** | Unclassified |
| **Panel** | General & Plastic Surgery |
| **Product Code** | FRO |
| **510(k) Number** | K133121 |

## 4. DEVICE DESCRIPTION

Axiostat is a single use, hemostatic dressing made of 100% chitosan. Chitosan is a well-known natural polysaccharide generally derived from shellfish which has widely recognized hemostatic properties. When applied on the bleeding site with firm pressure, the Axiostat

Chitosan Hemostatic Dressing acts as a mechanical barrier against bleeding. The Axiostat is intended for a maximum duration of use of 24 hours, including bandage changes that may be needed.

Axiostat is individually packaged in foil bags and sterilized using gamma irradiation. Axiostat is provided in six different sizes for over the counter use as listed below.

| **Axiostat Sizes** |
|---|
| 10 x 10 cm |
| 8 x 8 cm |
| 8 x 5 cm |
| 5 x 5 cm |
| 3.5 x 3.5 cm |
| 2 x 2 cm |

## 5. INDICATIONS FOR USE

Axiostat Chitosan Hemostatic Dressing is indicated to control bleeding of lacerations, minor cuts and abrasions.

## 6. NON-CLINICAL TESTING

The subject device has been evaluated through a series of nonclinical studies.

**A. Biocompatibility testing**:

Biocompatibility tests have been performed per the requirements of ISO 10993-1:2009, under the section "surface devices used in breached and compromised surfaces with limited exposure (≤24 hrs)". The following tests have been performed as per these requirements,

1. Cytotoxicity
2. Skin Irritation
3. Skin Sensitization
4. Acute Intravenous Systemic Toxicity
5. Acute Intraperitoneal Systemic Toxicity
6. Hemolysis Test
7. Pyrogenicity Test

**B. Heavy metal testing**

The subject device was tested for cadmium, lead, arsenic and mercury. The levels for all elements were found to be fewer than 1 ppm, which meets the USP-232 limits.

**C. Bench performance testing:**

1. Physical Properties
2. Absorbency Testing
3. Moisture Content

4. pH Testing
5. Tensile strength
6. *In-Vitro* Hemostatic Activity
7. *In Vivo* rabbit hemostasis study

## 7. STERILIZATION & PACKAGING

Axiostat Chitosan Haemostatic Dressing is supplied sterile in a foil bag. It is sterilized using gamma radiation to a sterility assurance level (SAL) of $10^{-6}$. Gamma sterilization validation was performed in compliance with the ISO 11137 Part-1:2006 and ISO 11137 Part-2:2013 standards.

Following the gamma sterilization, the packaging was subjected to sterile barrier testing to validate a shelf life of three (3) years as per ISO and ASTM standards.

a. The stability and effectiveness of packaging of the sterilized product during the shelf-life period was confirmed by real time stability studies and accelerated aging test, per ASTM F-1980.
b. Package seal strength (Wet/Dry) per ISO11607-1:2006
c. Dye penetration test as per ASTM F1929:15
d. Sterility test as per US Pharmacopeia <71>.

## 8. SUBSTANTIAL EQUIVALENCE DETERMINATION

The Axiostat Chitosan Hemostatic Dressing is substantially equivalent in intended use, indications for use, technology, material, design, packaging, sterilization, and performance claims to the predicate device, Chito-SAM™ Active (K133121). The following tables show the key characteristics of the subject and predicate devices.

**Table 1:** Comparison of technological characteristics of subject and predicate devices

| | **Subject device** | **Predicate device** | **Notes** |
|---|---|---|---|
| Manufacturer | Advamedica Inc. | SAM Medical Products | -- |
| Model/Trade Name | Axiostat Chitosan Hemostatic Dressing | Chito-SAM™ Active | -- |
| 510K Identifier | New device | K133121 | -- |
| Common Name | Hemostatic dressing | Hemostatic Dressing | Same |
| Classification | Unclassified | Unclassified | Same |
| Product Code | FRO | FRO | Same |
| Material | Chitosan | Chitosan | Same |
| Intended Use | Hemostasis | Hemostasis | Same |
| Indications for use | Axiostat Chitosan Hemostatic Dressing is indicated to control bleeding of lacerations, minor cuts and abrasions. | Chito-SAM™ Active is indicated to control bleeding of lacerations, minor cuts and abrasions. | Same |

| | | | |
|---|---|---|---|
| OTC/ Prescription | OTC | OTC | Same |
| Anatomical Site | External wounds | External wounds | Same |
| Package material | Foil Bag | Foil bag | Same |
| Sterilization | Gamma irradiation | Gamma irradiation | Same |
| Sizes | Axiostat:<br>10x10cm<br>8x8cm<br>8x5cm<br>5x5cm<br>3.5x3.5cm<br>2x2cm | 4 x 4-inch<br>3-inch x 6-foot Z-fold | -- |

**Table 2:** Comparison of biocompatibility tests on subject and predicate devices

| **Biocompatibility Tests** | **Subject device**<br>Axiostat Chitosan Hemostatic Dressing | **Predicate device**<br>Chito-SAM™ Active (K133121) |
|---|---|---|
| Cytotoxicity Test | Non-cytotoxic | Non-cytotoxic |
| Skin Irritation Study | Negative | Negative |
| Skin Sensitization Study | Negative | Negative |
| Acute Intravenous Systemic Toxicity Study | Negative | Negative |
| Acute Intraperitoneal Systemic Toxicity Study | Negative | Negative |
| Hemolysis | Negative | Negative |
| Pyrogenicity Test | Negative | -- |

The intended use and "Indications for Use" for the predicate device are identical to those of the Axiostat Chitosan Hemostatic Dressing. The chemical composition of the chitosan material in both products is the same. The technological and performance characteristics of the Axiostat are equivalent to the predicate device. No new issues regarding safety or efficacy are introduced by the Axiostat Chitosan Hemostatic Dressing.

## 9. SIMILARITY AND DIFFERENCES

The subject device has the following similarities to the predicate devices:

- ✓ the same intended use
- ✓ the same material (chitosan)
- ✓ same indications of use
- ✓ identical biocompatibility characteristics
- ✓ same sterilization method.

The minor differences in dimensions and form between the proposed device and predicate device do not affect the performance of proposed device or raise any safety concerns.

## 10. CONCLUSION

The Axiostat Chitosan Hemostatic Dressing shares its chemical composition and performance characteristics with the predicate device. The results of the performance testing confirm that the Axiostat Chitosan Hemostatic Dressing functions to its specifications, performs as intended, and exhibits the appropriate characteristics of a hemostatic dressing. The Axiostat is substantially equivalent to the predicate device in terms of materials, technological characteristics, intended use, indications for use, and performance. No new issues of safety or effectiveness are raised by the Axiostat Chitosan Hemostatic Dressing.