April 15, 2021

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

Re: K202830
Trade/Device Name: Axiostat Patch
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 7, 2020
Received: September 25, 2020

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,

Lixin Liu, 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)*
K202830

Device Name
Axiostat Patch

Indications for Use *(Describe)*
Axiostat Patch is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing for patients and for the rapid control of moderate to severe bleeding. The dressing is indicated for the following wounds: lacerations, abrasions, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

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 - K202830
AXIOSTAT PATCH

1. ADMINISTRATIVE INFORMATION

a. Date of preparation: 10 March 2021

b. Submitter: Advamedica Inc.
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Suite 400, Cambridge,
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c. Contact Person: Mr. Leo Mavely,
President, Advamedica Inc.
Email: office@advamedica.com
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d. Prepared By: Mr. Leo Mavely, President
Advamedica, Inc.

2. DEVICE NAME AND CLASSIFICATION

a. Trade/ Proprietary Name : Axiostat Patch

b. Common Name : Hemostatic 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

PREDICATES	PREDICATE 1	PREDICATE 2
510(k) Number	K150916	K102944
Trade/Proprietary	HemCon® Bandage PRO,	Coreleader Hemo-Pad

Name	HemCon® Patch PRO, HemCon® Strip PRO, HemCon® ChitoFlex PRO	
Manufacturer	HemCon Medical Technologies, Inc.	Coreleader Biotech Co. Ltd.
Classification Name	Dressing, Wound, Drug	Dressing, Wound, Drug
Regulatory Class	Unclassified	Unclassified
Product Code	FRO	FRO
Panel	General & Plastic Surgery	General & Plastic Surgery

4. DEVICE DESCRIPTION

The Axiostat Patch is a sterile, single use, non-absorbable hemostatic dressing. It is composed of chitosan a well-known natural polysaccharide generally derived from shellfish which has widely recognized hemostatic properties.

When applied directly to a wound with firm pressure, the dressing controls bleeding and provides a barrier against bacterial penetration. The hemostatic dressing can be removed after the clotting has occurred but should not remain on for more than 24 hours. The hemostatic dressing is not intended to be implanted.

The Axiostat Patch is equivalent in material, design, composition, manufacturing, intended use, sterilization, and biocompatibility to the legally marketed Axiostat Chitosan Hemostatic Dressing (K172324, cleared on 23rd Feb 2018). The only differences are the Indication for Use and the variations in size for this use.

The Axiostat Patch is individually packaged in moisture proof packs and terminally sterilized using gamma irradiation. The product may be cut to any size, and the company anticipates introducing the following sizes:

- 4 in x 4 in (10 cm x 10 cm)
- 3 in x 3 in (8 cm x 8 cm)
- 3 in x 2 in (8 cm x 5 cm)
- 2 in x 2 in (5 cm x 5 cm)
- 2 in x 1 in (5 cm x 2.5 cm)
- 1.4 in x 1.4 in (3.5 cm x 3.5 cm)
- 1 in x 1 in (2.5 cm x 2.5 cm)
- 0.8 in x 0.8 in (2 cm x 2 cm)
- 0.4 in x 3 in (1 cm x 8 cm)
- 0.4 in x 1.5 in (1 cm x 4 cm)

5. INDICATIONS FOR USE (Prescription use)

The Axiostat Patch is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing for patients and for the rapid control of moderate to severe bleeding. The dressing is indicated for the following wounds: lacerations, abrasions, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF SUBJECT AND PREDICATE DEVICES

The Axiostat Patch is technologically similar to the HemCon Patch Pro and the Coreleader Hemo-Pad. The Subject Device has the following similarities to one or both proposed predicate devices:

- Intended use
- Indications for use
- Mechanism of action
- Primary material
- Patient contacting material (chitosan)
- Biocompatibility
- Bacterial Barrier
- Sterilization method

Table 1: Comparison of technological characteristics of Subject and Predicate Devices

PARAMETER	SUBJECT DEVICE	PREDICATE 1	PREDICATE 2	SE
Manufacturer	Advamedica Inc.	HemCon, Inc.	Coreleader Biotech Co. Ltd.	-
Model/Trade Name	Axiostat Patch	HemCon Bandage PRO, HemCon Patch PRO, HemCon Strip PRO, Hemcon ChitoFlex PRO	Coreleader Hemo-Pad	-
510(k) Number	K202830	K150916	K102944	-
Product Code	FRO	FRO	FRO	Same
Common name	Hemostatic dressing	Wound dressing	Topical Hemostasis Pad	Same
Classification	Unclassified	Unclassified	Unclassified	Same
Primary Material	Chitosan	Chitosan	Chitosan	Same

Intended Use	Wound management	Wound management	Wound management	Same
Indications for Use	The Axiostat Patch is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing for patients and for the rapid control of moderate to severe bleeding. The dressing is indicated for the following wounds: lacerations, abrasions, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.	The HemCon® prescription devices are intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.	The Coreleader Hemo-Pad is a dressing indicated for topical wound management and for the external topical temporary control of moderate to severe bleeding. The dressing is indicated for the following wounds: abrasions, lacerations, skin surface puncture sites for vascular procedures (arteries and veins)	See Note 1
OTC/ Prescription	Prescription Only	OTC and Prescription	Prescription Only	Similar
Single Use	Yes	Yes	Yes	Same
Packaging	Moisture proof pouch	Foil Bags	Foil pouch	Similar. See Note 2
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Same
Shelf life	5 years	3 years	3 years	Different. See Note

				3
Biocompatibility Tests	Compliant to ISO 10993	Compliant to ISO 10993	Compliant to ISO 10993	Same
Size	Various	Various	Various	Same

Note 1:
Technologically, the Subject Device is similar to both the predicate devices. The Subject Device and the Predicate Device 1 have similar Indications for Use. Additionally, the Subject Device also includes indications for management of moderate to severely bleeding wounds. Hence, Predicate Device 2 is identified for this additional Indication for Use.

Note 2:
Differences in the packaging material do not raise any different device safety and performance issues. Additionally, the shelf life and package integrity of the product has been validated through real time stability studies.

Note 3:
The Subject Device has a shelf life of 5 years. This has been evaluated through real-time stability studies.

7. PERFORMANCE DATA

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

a. Biocompatibility testing

Biocompatibility tests have been performed 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 performed as per these requirements.

Table 2: Biocompatibility test details

Biocompatibility test	**Standard followed**	**Outcome**
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Skin Sensitization	ISO 10993-10	Non-toxic

Intracutaneous Reactivity	ISO 10993-10	Non-toxic
Acute Systemic Toxicity	ISO 10993-11	Non-toxic
Material-Mediated Pyrogenicity	ISO 10993-11	Non-pyrogenic
Bacterial Endotoxin Test	USP 85	Complies

b. Heavy metal testing

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

c. Bench performance testing

The Subject Device was evaluated through following bench tests.

Table 3: Bench performance testing

	Test	Test Method
1.	Appearance	In house protocol
2.	Moisture Content	In house protocol
3.	Absorbency	In house protocol
4.	pH	In house protocol
5.	Integrity test	In house protocol
6.	Tensile strength of product	In house protocol
7.	In vitro blood clotting test	In house protocol

d. Barrier to bacteria testing

This study was performed to evaluate the barrier to bacteria property of the Axiostat Patch. In this test, the Axiostat Patch (n=3) was used as a test sample and a similarly sized gauze (n=3) was used as the control sample. Samples were challenged with 10^6 cells of three gram-positive and three gram-negative bacterial species.
After challenging for the maximum use-life (i.e. 24 hrs.), the dressings were removed. Then, the plates without the dressing were incubated to observe for the presence/absence of bacterial growth. The following organisms were used:

- *Pseudomonas aeruginosa* (ATCC 9027)
- *Staphylococcus aureus* (ATCC 6538)
- *Escherichia coli* (ATCC 14169)

- *Enterococcus faecalis* (ATCC 29212)
- *Proteus mirabilis* (ATCC 12453)
- *Staphylococcus epidermidis* (ATCC 12228)

No bacterial growth was observed in the plates containing Axiostat Patch, whereas all plates containing cotton gauze showed bacterial growth. These results demonstrate the capacity of the Axiostat Patch to act as a barrier to bacterial penetration through the device.

e. Animal studies

The Axiostat Patch was evaluated using the animal testing procedures 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." This study was performed at an outside independent laboratory.

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. Further, there were no thrombi or blood clots in the lumens of blood vessels at the repair site in the Axiostat treated animals.

8. STERILIZATION AND PACKAGING

The Axiostat Patch 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 5 years. The stability and effectiveness of packaging of the sterilized product during the shelf life was confirmed by real time (to support 5-year shelf life) and accelerated stability studies.

The following tests were performed periodically in the validation of 5-year shelf life.

- Seal strength test as per ASTM F88.
- Dye penetration test as per ASTM F1929-15.
- Sterility test as per US Pharmacopeia <71>.
- Bacterial endotoxin test per US Pharmacopeia <85>.
- Bench performance tests to validate the shelf life of the product
  i. Appearance
  ii. Absorbency
  iii. pH testing
  iv. Moisture content
- Tensile strength for Patch

9. CONCLUSION

The Axiostat Patch is substantially equivalent to the predicate devices with respect to intended use, Indications for Use, design, material, sterilization, and biocompatibility.

The non-clinical testing data provided support the safety and performance of the device for the claimed Indications for Use statement. Hence, the minor differences between the Subject Device and the predicates do not raise any different device safety or performance issues.