Advamedica Inc.
% Ainoa Forteza
Vice Director Regulatory Consultant
Alira Health
Avinguda Josep Tarradellas, 123 (7th Floor), Barcelona, 08029 ESP

Re: K213198
Trade/Device Name: Ax-Surgi Surgical Hemostat
Regulation Number: 21 CFR 878.4454
Regulation Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use
Regulatory Class: Class II
Product Code: POD
Dated: September 28, 2021
Received: September 29, 2021

Dear Ainoa Forteza:

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 and Part 809); 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,

Deborah A. Fellhauer
-S

Deborah Fellhauer, RN, BSN
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

4. INDICATIONS FOR USE STATEMENT

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)*

Device Name
Ax-Surgi Surgical Hemostat

Indications for Use *(Describe)*
The Ax-Surgi is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (6/20) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) Summary

K213198

Ax-Surgi Surgical Hemostat

(per 21CFR 807.92)

Date: January 5, 2023

1. 510K APPLICANT / SUBMITTER

Advamedica Inc.,
Harvard Square,
1 Mifflin Place, Suite 400
Cambridge, MA 02138, USA
Email: office@advamedica.com
Telephone: +1 973-718-7575

2. SUBMISSION CONTACT PERSON

Ainoa Forteza
Alira Health
Avinguda Josep Tarradellas, 123 (7th Floor)
08029 Barcelona, Spain
Email: ainoa.forteza@alirahealth.com

3. DEVICE NAME

Proprietary Name: Ax-Surgi Surgical Hemostat
Common/Usual Name: Temporary, internal use hemostat
Classification Name: Non-absorbable hemostatic gauze for temporary internal use
Device Classification: II
Regulation Number: 21 CFR 878.4454
Product Code: POD

4. PREDICATE DEVICES

Primary Predicate- QuikClot Control+ Hemostatic Dressing – K200167

Reference Predicate – Axiostat Patch K202830

5. DEVICE DESCRIPTION

The Ax-Surgi Surgical Hemostat Surgical Hemostat is a sterile, single-use, surgical hemostatic patch. It is composed of a soft, lyophilized chitosan pad attached to a standard viscose-polyester gauze with a radiopaque element.

The lyophilized chitosan pad component of Ax-Surgi Surgical Hemostat is identical in material, composition, manufacturing, and biocompatibility to the legally marketed Axiostat Patch K202830, except that it is attached to a viscose-polyester gauze with a radiopaque element. The viscose-polyester gauze backing provides greater wet strength to the chitosan pad and the radiopaque element allows for detection via X-ray.

6. INTENDED USE

The Ax-Surgi Surgical Hemostat is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Ax-Surgi Surgical Hemostat is substantially equivalent to the predicate device, QuikClot Control+ Hemostatic Dressing, with respect to device characteristics and intended use. Table 5-1 on the next page provides a comparison of the technological and design characteristics of the subject device to the predicate.

Table 5-1: Comparison with Predicate Devices

	Subject Device	**Predicate Device**	**Reference Device**	**Comparison**
510(k) Number	K213198	K200167	K202830	
Trade Name	Ax-Surgi Surgical Hemostat	QuikClot Control+ Hemostatic Dressing	Axiostat Patch	
Manufacturer	Advamedica Inc.	Z-Medica LLC	Advamedica, Inc.	
Indications for Use	The Ax-Surgi Surgical Hemostat is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.	QuikClot Control+ is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries	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.	Same
Active Material	Chitosan	Kaolin	Chitosan	Similar The hemostatic agent in Ax-Surgi Surgical Hemostat uses chitosan while the hemostatic agent in the predicate QuikClot Control+ device is kaolin. See Note 1.

Device Design/ Composition	Chitosan pad attached to a rayon-polyester gauze backing containing a radiopaque thread	Non-absorbable device containing kaolin bound to gauze. The dressing is x-ray detectable.	Chitosan pad	Similar, the difference is not expected to raise any concerns in terms of safety and effectiveness. See Note 2.
Non-absorbable	Yes	Yes	Yes	Same
X-ray detectable	Yes	Yes	No	Same
Mechanism of Action	Absorption of plasma by the chitosan pad, which results in physical aggregation of blood cells and clotting factors at the site of application. In addition, when applied with pressure, Ax-Surgi Surgical Hemostat creates a mechanical barrier against bleeding	Hemostasis is achieved through the activity of the hemostatic agent kaolin bound to the gauze in conjunction with compression	Absorption of plasma by the chitosan pad, which results in physical aggregation of blood cells and clotting factors at the site of application. In addition, when applied with pressure, Axiostat Patch creates a mechanical barrier against bleeding	Similar, the difference is not expected to raise any concerns in terms of safety and effectiveness. See Note 3.
Sterilization method	Gamma radiation	Gamma radiation	Gamma radiation	Same

Note 1:
Both chitosan and kaolin are non-absorbable hemostatic materials., therefore the difference in the hemostatic agent between the subject and predicate device presents no additional issues of safety or effectiveness.

Note 2:
Both the proposed and primary predicate devices are composed of materials that are demonstrated to be biocompatible and hemostatic. The use of chitosan in the proposed Ax-Surgi Surgical Hemostat device compared to kaolin-impregnated gauze does not present any new issues of safety or effectiveness as evident from the extensive pre-clinical, biocompatibility, animal testing and predicate device. The proposed Ax-Surgi Surgical Hemostat and the reference device, Axiostat Patch are identical in design in that both pads are composed of 100% chitosan. The proposed Ax-Surgi Surgical Hemostat differs in that it is attached to a viscose-polyester gauze backing containing a radiopaque thread to support the revised indications for use. These are minor differences; however, biocompatibility testing has been conducted that demonstrated the backing is safe for its intended use and that there are no new issues of safety.

Note 3:
Both Ax-Surgi Surgical Hemostat and the predicate QuikClot Control+ Hemostatic Dressing device function by achieving hemostasis by physical means through the activity of a hemostatic agent in conjunction with compression. Both the proposed Ax-Surgi Surgical Hemostat and the predicate QuikClot Control + devices are to be used to apply pressure to an internal wound until bleeding is controlled. The hemostatic agent in Ax-Surgi Surgical Hemostat uses chitosan while the hemostatic agent in the predicate QuikClot Control+ device is kaolin. Both the proposed Ax-Surgi Surgical Hemostat and the Axiostat Patch reference device are identical in that they operate by absorption of plasma by the chitosan pad, which results in physical aggregation of blood cells at the site of application. In addition, when applied with pressure, both devices create a mechanical barrier against bleeding.

Non-clinical testing has been conducted to demonstrate the safety and performance of Ax-Surgi Surgical Hemostat. The results from all the testing conducted confirms that Ax-Surgi Surgical Hemostat is as safe and as effective as the predicate in its intended use and that it is substantially equivalent to the predicate and reference devices.

8. PERFORMANCE TESTING

Table 5-2 lists all of the testing that has been performed on Ax-Surgi Surgical Hemostat.

Table 5-2: Ax-Surgi Surgical Hemostat Testing

Testing	Results
Cytotoxicity	Non-cytotoxic
Sensitization	Non-sensitizing
Genotoxicity	Non-mutagenic
Acute Systemic Toxicity	Non-toxic
Implantation	Non-toxic
Pyrogenicity	Non-pyrogenic
Subacute Toxicity	Non-toxic
Intracutaneous Reactivity	Non-irritating
Hemolysis Test	Non-hemolytic
Animal Studies ● Pilot study on "To evaluate the safety and performance of chitosan hemostatic dressing in non- heparinized porcine hepatic resection model (48hr and 28 days non-GLP)" ● Pivotal study on "Evaluation of Safety and Hemostatic Performance of the Ax-Surgi Chitosan Surgical Hemostat in a Liver Resection Model in Swine, 48 Hours and 28 Day."	Ax-Surgi Surgical Hemostat achieved successful safety and performance assessment in a pilot non-GLP and a pivotal study conducted in porcine hepatic resection model. Both the pilot and pivotal animal studies demonstrated that the Ax-Surgi Surgical Hemostat was safe to be used as a hemostatic dressing for temporary internal use. During the pivotal study, Ax-Surgi Surgical Hemostat achieved successful hemostasis in a swine liver resection model displaying class III or class IV bleeding. The hemostatic performance and safety of Ax-Surgi Surgical Hemostat was compared with the standard of care as control group. This study evaluated inflammation, adhesion formation, systemic and local toxicity according to ISO 10993-06 and ISO 10993-11 and the local effect after implantation as compared to the predicate device. The preclinical studies demonstrated that the subject device is; • Able to achieve hemostasis • Can be radiographically detected • Inflammation and adhesions associated with the device were as expected for this type of surgery (laparotomy and liver resection) and were substantially equivalent to the standard of care. • No evidence of vascular obstruction or embolization The results of the study were satisfactory and met necessary safety end points as per special controls mentioned in Regulation no. 21 CFR 878.4454 and the study results support the substantial equivalence of the device.

Moisture Content	Pass
Tensile Strength	Pass
Integrity	Pass
Radiopacity	Pass
In vitro Clot Assessment	Pass
Particulate Release	Pass
Absorbency	Pass
pH	Pass

9. STERILIZATION AND PACKAGING

Ax-Surgi Surgical Hemostat is provided sterile in a moisture proof packs. The product is terminally sterilized gamma sterilization 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 18 months. The stability and effectiveness of packaging of the sterilized product during the shelf life was confirmed by real time study.

After a real time, aging period of 18 months, testing conducted demonstrates that Ax-Surgi Surgical Hemostat retains sterility, functionality, and its physical characteristics. The tests results demonstrate that Ax-Surgi Surgical Hemostat dressings stored for a period of 18 months are safe and effective for their intended use.

10. CONCLUSION

The subject device complies with special controls as identified in 21 CFR 878.4454 "Non-absorbable, hemostatic gauze for temporary internal use". Based on the information provided in this 510(k) premarket notification, Advamedica Inc. concludes that Ax-Surgi Surgical Hemostat is substantially equivalent to the predicate device, QuikClot Control+ Hemostatic Dressing.