August 24, 2023

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

Re: K212766
Trade/Device Name: Maxiocel Chitosan Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 26, 2023
Received: April 27, 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,

David Krause -S

David Krause, Ph.D.
Deputy Director
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)*
K212766

Device Name
Maxiocel Chitosan Wound Dressing

Indications for Use *(Describe)*

The Maxiocel Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic and acute wounds and to provide a barrier against bacterial penetration.

Under medical supervision, the Maxiocel Chitosan Wound Dressing may be used for the management of the following wounds:
• Pressure sores
• Diabetic ulcers
• Leg ulcers
• Donor sites and graft sites
• Surgical wounds
• Skin abrasions and lacerations
• 1st and 2nd degree bums
• Trauma wounds

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.

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SECTION 05

510(k) Summary

510(k) SUMMARY

MAXIOCEL CHITOSAN WOUND DRESSING

1. ADMINISTRATIVE INFORMATION

a. Date of preparation	**:**	07/08/2023
b. Submitter	**:**	Advamedica Inc. Harvard Square, 1 Mifflin Place, Suite 400, Cambridge, Massachusetts 02138, USA. Phone: +1 973-718-7575 Fax: +1 888-584-8237
c. Contact Person	**:**	Mr. Leo Mavely, President, Advamedica Inc. 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 Name	**:**	Maxiocel Chitosan Wound Dressing
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

	Primary Predicate Device	**Secondary Predicate Device**
Proprietary/Trade name	KA01 Chitosan Wound Dressing	AQUANOVA Super-Absorbent Dressing
Manufacturer	Foshan United Medical Technologies LTD	Medtrade Products Ltd. Crewe Business Park Crewe, Cheshire CWl 6GL United Kingdom
Decision Date	26/01/2015	25/07/2007
Classification Name	Unclassified	Unclassified
Device Class	Dressing, Wound, Drug	Dressing, Wound, Drug
Product Code	FRO	FRO
Panel	General & Plastic Surgery	General & Plastic Surgery
510(k) Number	K143124	K070175

4. IDENTIFICATION OF REFERENCE DEVICE

Table 2: Reference device details

	Reference Device
Proprietary/Trade name	Axiostat Patch
Manufacturer	Advamedica Inc.
Decision Date	15/04/2021
Classification Name	Unclassified
Device Class	Unclassified
Product Code	FRO
Panel	General & Plastic Surgery
510(k) Number	K202830

5. DEVICE DESCRIPTION

The Maxiocel Chitosan Wound Dressing is a soft, sterile, single-use absorbent gelling wound dressing used for absorption of wound exudate. The Maxiocel Chitosan Wound Dressing helps in maintaining a moist, optimal wound healing environment, helps in autolytic debridement, and is easy to remove. The Maxiocel Chitosan Wound Dressing is provided both in prescription (Rx) and over-the-counter (OTC) forms.

The Maxiocel Chitosan Wound Dressing can be kept on the wound site for up to 7 days. Dressings are individually packed in moisture-proof pouches and terminally sterilized using gamma radiation to achieve a SAL 10^{-6}. The Maxiocel Chitosan Wound Dressing can be manufactured in different sizes and are currently available in the following sizes.

- 18” x 18” (45 cm x 45 cm)
- 8” x 12” (20 cm x 30cm)
- 6” x 6” (15 cm x 15 cm)
- 4” x 4” (10 cm x 10 cm)
- 2” x 4” (5 cm x 10 cm)
- 2’’x 2’’ (5 cm x 5cm)
- 1’’x2’’ (2.5 cm x 5cm)
- 1’’x1’’ (2.5 cm x 2.5 cm)
- 1” x 12” (2.5 cm x 30 cm)

6. INDICATIONS FOR USE

6.1. Prescription Use

The Maxiocel Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic and acute wounds and to provide a barrier against bacterial penetration.

The Maxiocel Chitosan Wound Dressing can be used in the control of minor bleeding.

Under medical supervision, the Maxiocel Chitosan Wound Dressing may be used for the management of the following wounds:

- Pressure sores
- Diabetic ulcers
- Leg ulcers

- Donor sites and graft sites
- Surgical wounds
- Skin abrasions and lacerations
- 1st and 2nd degree partial thickness burns
- Trauma wounds

6.2. Over the Counter Use

The Maxiocel Chitosan Wound Dressing is indicated for the management of

- Minor cuts
- Minor scalds and 1st-degree burns
- Abrasions
- Lacerations

and to provide a barrier against bacterial penetration.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF SUBJECT AND PREDICATE DEVICES

Table.3- Comparison of technological characteristics of Subject and Predicate devices

	Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Similarity**
Manufacturer	Advamedica Inc.	Foshan United Medical Technologies LTD	Medtrade Products Ltd. Crewe Business Park Crewe, Cheshire CWl 6GL United Kingdom	-
Model/Trade Name	Maxiocel Chitosan Wound Dressing	KA01 Chitosan Wound Dressing	AQUANOVA Super-Absorbent Dressing	-
510k Number	To be issued	K143124	K070175	-
Product Code	FRO	FRO	FRO	Same
Common Name	Wound Dressing	Wound Dressing	Wound Dressing	Same
Classification	Unclassified	Unclassified	Unclassified	Same

Primary Material	Chitosan	Chitosan	Chitosan	Same
Indications for Use	**Prescription use:** The Maxiocel Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic and acute wounds and to provide a barrier against bacterial penetration. The Maxiocel Chitosan Wound Dressing can be used in the control of minor bleeding. Under medical supervision, the Maxiocel Chitosan Wound Dressing may be used for the management of the following wounds: ● Pressure sores ● Diabetic ulcers ● Leg ulcers ● Donor sites and graft sites ● Surgical wounds ● Skin abrasions and lacerations ● 1st and 2nd degree partial thickness burns ● Trauma	**Prescription use:** The KA01 Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds. Under medical supervision, the KA01 Chitosan Wound Dressing may be used for the management of: ● Pressure sores ● Diabetic ulcers ● Leg ulcers ● Donor sites and graft sites ● Surgical wounds ● Skin abrasions and Lacerations ● 1st and 2nd-degree burns ● Trauma wounds	**Prescription use:** Under the supervision of a healthcare professional AQUANOVA may be used for wounds such as leg ulcers (Stages I - IV), diabetic ulcers, surgical wounds (post - operative, donor sites, dermatological burns (first and second degree), and the management of surgical or traumatic wounds which have been left to heal by secondary intention. AQUANOVA may also be used for the local management of wounds that are prone to bleeding such as wounds that have been surgically or mechanically debrided, donor sites, and traumatic wounds. AQUANOVA can be used in the control of minor	Same. See Note 1

	wounds **Over-the-counter use:** The Maxiocel Chitosan Wound Dressing is indicated for the management of ● Minor cuts ● Minor scalds and 1st degree burns ● Abrasions ● Lacerations and to provide a barrier against bacterial penetration.	**Over-the-counter use:** The KA01 Chitosan Wound Dressing may be used for the management of: ● Minor cuts Minor scalds and 1st-degree burns ● Abrasions ● Lacerations	bleeding. **Over-the-counter use:** AQUANOVA Super-Absorbent OTC is indicated for minor burns, superficial cuts, lacerations and abrasions, and minor irritations of the skin.	
Anatomical Site	Surface wounds	Surface wounds	Surface wounds	Same
OTC	Yes	Yes	Yes	Yes
Prescription	Yes	Yes	Yes	Yes
Contact duration	The Maxiocel Chitosan Wound Dressing can remain on-site for up to 7 days, depending on the level of exudate.	The KA01 Chitosan wound dressing can remain in situ for up to 7 days, depending on the level of exudate.	Not provided	Same. See Note 2
Mechanism of Action	Conformable, highly absorbent dressing that forms a soft clear gel on contact with wound exudate which maintains a moist environment for optimal wound healing, provides	Conformable, highly absorbent dressing that forms a soft clear gel on contact with wound exudate which maintains a moist environment for	It is a soft pad that gels in the presence of fluids to absorb large quantities of exudate and produce a moist wound healing environment.	Same

	patient comfort and allows painless removal.	optimal wound healing provides patient comfort and allows painless intact removal.		
Biocompatibility (ISO 10993)	Yes	Yes	Yes	Same. See Note 3
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Same
Single-Use	Yes	Yes	Yes	Same
Shelf Life	3 years	Not included	Not included	See Note 4

Note 1:

Both the Maxiocel Chitosan Wound Dressing and the predicate devices form a gel when they contact the wound exudate, which maintains a moist environment for optimal wound healing.

Additionally, both the Maxiocel Chitosan Wound Dressing and the reference device form a gel when they contact the wound exudate, which provides a barrier against bacteria.

This difference in Subject Device holding an additional claim, however, does not raise questions on safety and effectiveness due to proven test results (Barrier to Bacteria Testing).

As a result, the addition of minor bleeding and barrier to bacterial claims in the Maxiocel Chitosan Wound Dressing do not raise any concerns about its safety and efficacy.

Note 2:

The contact duration of AQUANOVA Super-Absorbent Dressing is not provided in the 510(k) summary.

Note 3:

The biocompatibility testing of AQUANOVA Super-Absorbent Dressing is not provided in the 510(k) summary.

Note 4:

The shelf life of the KA01 and AQUANOVA Super-Absorbent Dressing is not provided in the 510(k) summary.

8. PERFORMANCE DATA

The performance testing demonstrates that the Subject Device performs as intended under anticipated conditions of use. The Subject Device has been evaluated through a series of nonclinical studies to determine whether it meets the acceptance criteria for its intended applications. These tests are summarized below.

8.1. Biocompatibility testing

Biocompatibility tests have been performed per the requirements of ISO 10993-1:2018, under the section "Surface devices used on breached or compromised surfaces" with "limited contact duration (24 hours ≤ 30 days)". The following tests have been carried out as per these requirements.

Table.5- Summary of Biocompatibility Tests

S.No.	Biocompatibility test	Standard followed	Outcome
1	Cytotoxicity	ISO 10993-5	Non-cytotoxic
2	Skin Sensitization	ISO 10993-10	Non-sensitizer
3	Skin irritation	ISO 10993-10	Non-irritant
4	Acute Systemic Toxicity	ISO 10993-11	Non-toxic
5	Bacterial Endotoxin Test	USP 85 & USP 161	Complies

8.2. 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].

8.3. Bench performance testing

The Subject Device was evaluated through the following bench tests.

Table.6- Bench performance testing

S. No	Test	Test Method

1.	Appearance	In house protocol
2.	Moisture Content	ASTM E 1868-10
3.	Absorbency	BS EN 13726-1:2002
4.	pH	BS EN 13726-1:2002
5.	Dispersion Test	BS EN 13726-1:2002
6.	Fluid Retention Test	BS EN 13726-1:2002
7.	Tensile strength	EN 29073-3 and ISO 9073-18

9. BACTERIAL BARRIER TESTING

This study was performed to evaluate the barrier to bacteria property of the Maxiocel Chitosan Wound Dressing. In this test, the Maxiocel Chitosan Wound Dressing (n=3) was used as a test sample and a similarly-sized gauze (n=3) was used as a control sample. Samples were challenged with 10^6 cells of three gram-positive and three gram-negative bacterial species. After challenging for 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.

- Staphylococcus aureus (ATCC 29737)
- Staphylococcus epidermidis (ATCC 12228)
- Micrococcus luteus (ATCC 9341)
- Pseudomonas aeruginosa (ATCC 9027)
- Escherichia coli (ATCC 14169)
- Proteus mirabilis (ATCC 12453)

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

10. STERILIZATION AND PACKAGING

The Maxiocel Chitosan Wound Dressing is packed in a moisture-proof pack. The product is terminally sterilized using gamma radiation ensuring 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 3 years. The stability and effectiveness of packaging of the sterilized product during the shelf-life was confirmed by real-time (to support 3-year shelf life) stability studies.

The following tests were performed periodically in the validation of the 3-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 as per US Pharmacopeia <85> and Medical devices - Bacterial Endotoxin and Pyrogen Tests as per USP <161>
- Bench performance tests to validate the shelf-life of the product.
    i. Appearance
    ii. Moisture Content
    iii. Absorbency
    iv. pH Test
    v. Dispersion Test
    vi. Fluid Retention
    vii. Tensile Strength

11. CONCLUSION

The Maxiocel Chitosan Wound Dressing is substantially equivalent to the Predicate Devices with respect to intended use, indications for use, design, material, sterilization, and biocompatibility and the reference device in terms of barrier against bacterial penetration, 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 difference between the Subject and Predicate Device do not raise any different device safety or performance issues.