October 11, 2023

Maxigen Biotech, Inc.
Cheng-Han Chou
Regulatory Affairs
No. 88, Keji 1st Rd., Guishan District
Taoyuan City, 333411
Taiwan

Re: K223126
Trade/Device Name: SurgiAid® Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 12, 2023
Received: July 13, 2023

Dear Cheng-Han Chou:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K223126

Device Name
SurgiAid Collagen Wound Dressing

Indications for Use *(Describe)*
SurgiAid Collagen Wound Dressing is indicated for use in patients who have surgical wounds, donor sites/grafts, podiatric wound, wound dehiscence, traumatic wounds, abrasions, lacerations, partial thickness burns or skin tears. SurgiAid Collagen Wound Dressing can be applied to wounds with depth less than 0.3 cm.

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 (K223126)

Date of Summary revised：October 11, 2023

1. SUBMITTER TYPE INFORMATION：

Name：Maxigen Biotech Inc.
Address：No.88, Keji 1st Rd., Guishan Dist., Taoyuan City 333, Taiwan (R.O.C.)
Phone：886-3-3287222
Fax：886-3-3287333
Contact：Cheng Han, Chou

2. DEVICE：

Name：SurgiAid Collagen Wound Dressing
Common Name：Collagen Wound Dressing
Classification Regulation/Class：Unclassified
Product Code：KGN
Panel：General & Plastic Surgery

3. PREDICATE DEVICE：

Predicate device：SurgiAid Collagen Wound Dressing (K100927)
Reference device：SkinTemp II Dressing (K122325)

4. DEVICE DESCRIPTION：

SurgiAid Collagen Wound Dressing (SurgiAid) is white, porous pliable and absorbable collagen wound dressing. It is fabricated by fibrous collagen matrix which is purified from bovine Achilles tendon. SurgiAid is pliable and can be applied easily to clean wound. The product is supplied in sterile, non-pyrogenic package, and is indicated for single use only.

5. INDICATIONS FOR USE：

SurgiAid® Collagen Wound Dressing is indicated for use in patients who have surgical wounds, donor sites/grafts, podiatric wound, wound dehiscence, traumatic wounds, abrasions, lacerations, partial thickness burns or skin tears. SurgiAid® Collagen Wound Dressing can be applied to wounds with depth less than 0.3 cm.

6. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS

The subject device has the same characteristics as the predicate device in terms of raw materials, nature of sterile barrier system as well as sealing process, sterilization method, shelf-life, indication for use, operation and thickness of device. The different is identified in dimension of device and addition of eight new size in this submission. Please refer to Table 1 for comparison of the subject device and predicate device. The introduction of new dimensions in SurgiAid does not affect the intended use, performance test and fundamental scientific technology of the device.

Table 1. Substantial Equivalence Comparison of SurgiAid Collagen Wound Dressing of the predicate device.

Item	Subject Device	Predicate Device	Reference Device	Comparison
	SurgiAid Collagen Wound Dressing	SurgiAid Collagen Wound Dressing	SkinTemp II Dressing	
Manufacturer	MAXIGEN BIOTECH INC.	MAXIGEN BIOTECH INC.	Human Biosciences,Inc.	Identical to Predicate Device
510(k) No.	K223126	K100927	K122325	N/A
Product Code	KGN	KGN	KGN	Identical
Classification name	Collagen Wound Dressing	Collagen Wound Dressing	Collagen Wound Dressing	Identical
Indications for use	SurgiAid ® Collagen Wound Dressing is indicated for use in patients who have surgical wounds, donor sites/grafts, podiatric wound, wound dehiscence, traumatic wounds, abrasions, lacerations, partial thickness burns or skin tears. SurgiAid ® Collagen Wound Dressing can be applied to wounds with depth less than 0.3 cm	SurgiAid ® Collagen Wound Dressing is indicated for use in patients who have surgical wounds, donor sites/grafts, podiatric wound, wound dehiscence, traumatic wounds, abrasions, lacerations, partial thickness burns or skin tears. SurgiAid ® Collagen Wound Dressing can be applied to wounds with depth less than 0.3 cm	The HBS SkinTemp II Dressing is indicated for the management of burns, sores, blisters, scrapes, ulcers, and other wounds.	Identical to Predicate Device

Materials	Bovine (Achilles) tendon type I collagen	Bovine (Achilles) tendon type I collagen	Type I bovine collagen	Identical to Predicate Device
Form	Sheet	Sheet	Sheet	Identical
Specifications	15mm x 20mm x 0.5mm 20mm x 30mm x 0.5mm 25mm x 30mm x 0.5mm 30mm x 40mm x 0.5mm 100mm x 100mm x 0.5mm 20mm x 40mm x 3.0mm 30mm x 30mm x 3.0mm 40mm x 50mm x 3.0mm 50mm x 50mm x 3.0mm 100mm x 100mm x 3.0mm	20mm x 40mm x 3.0mm 20mm x 30mm x 3.0mm	2" x 2" 3" x 4" 8" x 12"	The sizes of the subject device fall within the size range of the reference device
Usage type	Single use only	Single use only	Single patients use	Identical
Sterilization	By gamma irradiation	By gamma irradiation	Each dressing is sterilized using Electron Beam Sterilization	Identical to Predicate Device
Design	White, porous, pliable, absorbable, sterile, non-pyrogenic package collagen wound dressing and it is indicated for single use only.	White, porous, pliable, absorbable, sterile, non-pyrogenic package collagen wound dressing and it is indicated for single use only.	Soft, sterile, disposable, absorbent & confirmable single use wound dressing with non-adherent backing	Identical to Predicate Device
Biocompatibility	All biocompatibility evaluations of SurgiAid were conforms to the requirements specified in ISO10993	All biocompatibility evaluations of SurgiAid were conforms to the requirements specified in ISO10993	All testing was performed as per FDA biocompatibility guidance on ISO10993	Identical
Shelf life	Three years	Three years	Five years	Identical to Predicate Device
Sterile Barrier Packaging	Double blister tray as Sterile Barrier System	Double blister tray as Sterile Barrier System	It is packed in primary packaging in the form of a Tyvek pouch (1059B) and is then	Identical to Predicate Device

			packed in secondary packing for additional protection	
Storage condition	Store in a dry place below 25°C	Store in a dry place below 25°C	Store in a cool and dry place	Identical to Predicate Device
Performance	● Water absorption (>25 fold) ● Porosity (>80%) ● Density (About 37 mg/cm^3)	● Water absorption (>25 fold) ● Porosity (>80%) ● Density (About 37 mg/cm^3)	NA	Identical to Predicate Devic

7. NON-CLINICAL PERFORMANCE DATA：

The subject device is technically identical to the predicate device regarding materials, indications for use, form, sterilization, packaging and storage conditions. The only difference is the addition of new dimension. Any potential new risks raised with the new dimension have been identified and addressed with verification and validation activities to ensure that substantial equivalence is still established in technological characteristics.

The following non-clinical performance test evaluation associated with physicochemical and microbial properties, biocompatibility, sterilization, packaging and stability were conducted on SurgiAid Collagen Wound Dressing (subject device). The subject device is comprised of the same materials and undergo the same manufacturing process as the predicate device but different in dimensions simply caused by physical cutting.

The Biocompatibility evaluations including cytotoxicity, genotoxicity, acute systemic toxicity, sub chronic systemic toxicity, irritation reactivity, sensitization and pyrogen for the subject device were in accordance with ISO10993-1:2018. All results were acceptable. Moreover, the evaluation of sterilization, product/packaging stability (packaging- burst test, creep test, seal strength, dye penetration and sterility) and product characteristics testing (dimension, bioburden, endotoxin, thermal characteristics, collagenase resistance heavy metal value, lipid, carbohydrate, pepsin resistance and pH) has been completed and these results were leveraged to demonstrate the substantial equivalence between the subject device and predicated device. All tests were met acceptance criteria in according with related standards.

8. Conclusion

SurgiAid Collagen Wound Dressing (subject device) has the same fundamental scientific technology and indications for use as the originally cleared SurgiAid (predicate device) in terms of product's designs, biocompatibility, raw material used, manufacturing process, primary composition, performance, packaging and sterilization method based on declaration of conformity to pre-established design control requirements and on a risk assessment of the changes to predicate device. The only modification for the subject device is the addition of new dimensions to the predicate device that is also derived from the same component material. Existing biocompatibility, sterilization validation and stability test performed on predicated device could be leveraged without affecting safety and efficacy of subject device. No additional new risk with respect to safety and efficacy of subject device is identified in the course of introduction of new dimensions. Consequently, SugiAid Collagen Wound Dressing (subject device) is substantially equivalent to the predicate SurgiAid cleared under K100927.