November 22, 2023

Maxigen Biotech Inc.
Cheng-Han Zhou
Regulatory Affairs
No.88, Keji 1st Rd., Guishan Dist.
Taoyuan, 33383
TAIWAN

Re: K230529
Trade/Device Name: HealiAid ® Dental Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: OLR
Dated: October 30, 2023
Received: October 31, 2023

Dear Cheng-Han Zhou:

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K230529

Device Name
HealiAid® Dental Collagen Wound Dressing

Indications for Use *(Describe)*
HealiAid® Dental Collagen Wound Dressing is indicated for the management of oral wounds and sores, including:

1. Denture sores
2. Oral ulcers (non-infected or viral)
3. Periodontal surgical wounds
4. Extraction sites
5. Surgical wounds.
6. Traumatic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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20th November, 2023

510(k) Summary (K230529)

Date of revised: November 22, 2023

1 Submitter

Name: Maxigen Biotech Inc.

Address: No.88, Keji 1st Rd., Guishan Dist., Taoyuan City, Taiwan

Telephone: (03)328-7222 #1251

Fax: (03) 328-7333

Contact: Cheng-Han Zhou / RA

2 Device Name:

Trade name:	HealiAid® Dental Dental Collagen Wound Dressing
Classification Name:	Oral Wound Dressing
Common Name:	Dental Collagen Wound Dressing
Product Code:	OLR
Regulation Number:	NA
Class:	Unclassified
Review Panel:	Dental

3 Legally marketed to which substantial equivalence is claimed

Predicate devices: neoTape/neoPlug/neoCote Collagen Dental Wound Dressing (K152600) marketed by Collagen Matrix Inc.

Reference devices: SurgiAid/HealiAid® Dental Collagen Wound Dressing (K100927) marketed by Maxigen Biotech Inc.

4 Device Description

The subject device is HealiAid® Dental Collagen Wound Dressing (HealiAid Dental) that is a white, porous, pliable and absorbable collagen wound dressing. HealiAid Dental is fabricated by fibrous collagen matrix purified from bovine

Achilles tendons. HealiAid Dental is pliable and can be applied easily to oral wounds to protect the wound bed. The product is supplied in a sterile, non-pyrogenic package, and is indicated for single use only.

5 Intended Use

HealiAid® Dental Collagen Wound Dressing is indicated for the management of oral wounds and sores, including:

- Denture sores
- Oral ulcers (non-infected or viral)
- Periodontal surgical wounds
- Extraction sites
- Surgical wounds
- Traumatic wounds

6 Comparison of technical characteristics and substantial equivalence discussion

The following tables provide a summary of substantial equivalence between the subject device and predicate device, neoTape/neoPlug/neoCote Collagen Dental Wound Dressing (K152600) manufactured by Collagen Matrix Inc. Tthe technological characteristics of HealiAid Dental and neoTape/neoplug/neoCote are similar in terms of instruction for use, composition, collagen source, sterilization method, etc. HealiAid Dental exhibited substantially equivalent characteristics to the predicate device that do not raise significant concern about substantial equivalence.

HealiAid Dental applied in oral cavity is submitted to obtain the clearance for new indication from a previously FDA-cleared device, SurgiAid/HealiAid Collagen Wound Dressing (SurgiAid) (K100927) manufactured by Maxigen Biotech Inc. HealiAid Dental is identical to the SurgiAid in the composition, manufacturing process, sterilization, packaging materials and acceptance criteria of final inspections, geometry and technical characteristics.

Table 1. Comparison of Technical Characteristics.

	Subject Device	Predicate Device	Reference device
Product	HealiAid® Dental Collagen Wound Dressing	neoTape®/neoPlug®/ neoCote® Collagen Dental Wound Dressing	SurgiAid® Collagen Wound Dressing
Manufacturer	Maxigen Biotech Inc.	Collagen Matrix, Inc.	Maxigen Biotech Inc.
K number	K230529	K152600	K100927
Classification Product Code	OLR	KGN	KGN
Indications for Use	intended for the management of wounds including: 1. Denture sores 2. Oral ulcers (non-infected or viral) 3. Periodontal surgical wounds 4. Extraction sites 5. Surgical wounds 6. Traumatic wounds	intended for the management of wounds including: 1. Denture sores 2. Oral ulcers (non-infected or viral) 3. Periodontal surgical wounds 4. Suture sites 5. Burns 6. Extraction sites 7. Surgical wounds Traumatic wounds	intended for the management of wounds including: 1. Surgical wounds 2. Donor/sites/grafts podiatric wounds 3. Wound dehiscence 4. Traumatic wounds 5. Abrasions 6. Lacerations 7. Partial thickness burns 8. Skin tears Wounds with depth less than 0.3 cm
Material	Purified collagen	Purified collagen	Purified collagen
Collagen source	Bovine	Bovine	Bovine
Form	Porous collagen sponge	Porous collagen sponge	Porous collagen sponge
Color	White to light-yellow	White to light-yellow	White to light-yellow
Shapes	Rectangular sheet and plug type	Rectangular sheet and plug type	Rectangular sheet and plug type
Absorbency	Absorbs local wound fluids upon application	Absorbs local wound fluids upon application	Absorbs local wound fluids upon application
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic	Non-Pyrogenic
Sterilization	Gamma irradiation, SAL 10^{-6}	Gamma irradiation, SAL 10^{-6}	Gamma irradiation, SAL 10^{-6}
Packaging	Sheet: double barrier Plug: Single barrier (Blister tray and Tyvek)	Single barrier (Blister tray and Tyvek)	Sheet: double barrier Plug: Single barrier (Blister tray and Tyvek)

Storage	Subject device should be stored at room temperature.	Predicate device should be stored at 15-30 ℃.	Reference device should be stored at room temperature.
Single use / Reuse	Single use only.	Single use only.	Single use only.
Implantation duration and timecourse of degradation	It degrades within 30 days and is implanted for a maximum of 30 days in oral cavity.	It degrades within 30 days and is implanted for a maximum of 30 days in oral cavity.	Not applicable.

7 Performance data

7.1 Non-clinical studies

HealiAid Dental has been subjected to extensive pre-clinical testing to assess the biocompatibility of the device. Biocompatibility evaluations include cytotoxicity, genotoxicity, systemic toxicity, irritation, sensitization, implantation in accordance with ISO 10993-1: 2018. The results verified that HealiAid Dental comply with the corresponding requirements.

Study		**Test Method / Model**	**Results**
Cytotoxicity		L929 MEM Elution, ISO 10993-5	Non-cytotoxic.
Genotoxicity		Salmonella Typhimurium Reverse Mutation Assay Ames test, ISO 10993-3	Non-genotoxic.
		In Vitro Mammalian Cell Gene Mutation Test Using Mouse Lymphoma (L5178Y) Cells, ISO 10993-3	Non-genotoxic.
		In Vivo Mammalian Erythrocyte Micronucleus Test, ISO 10993-3	Non-genotoxic.
Systemic toxicity	Acute systemic toxicity	Acute Systemic Toxicity Study in Mice, ISO 10993-11	No acute systemic toxicity.
	Subchronic systemic toxicity	A Dual Route Subchronic Systemic Toxicity Study in Rats, ISO 10993-11	No subchronic systemic toxicity.
Irritation		Intracutaneous reactivity in Rabbits, ISO 10993-23	Non-irritant.

Sensitization	Guinea Pig Maximazation, ISO 10993-10	Non-sensitizing.
Implantation	Implantation Study in Porcine gingiva. ISO 10993-6	Very slight or non-tissue reaction.
Material mediated pyrogenicity	Pyrogen Study in Rabbits, USP 151	Non-pyrogenic

The pre-clinical evaluations have demonstrated the substantial equivalence with the predicate device, including collagen content, carbohydrate analysis, *in vitro*/*in vivo* degradation test, pH value analysis, thermal stability analysis, microstructure analysis, moisture content analysis and water absorption measurement etc. In comparative testing in the porcine gingiva model, the subject device, HealiAid® Dental, exhibited a similar timecourse of degradation compared to the predicate device, neoTape®/neoPlug®/ neoCote®.

The validation of shelf life, sterilization, and devices containing animal-derived material, were also conducted in the following laboratory studies:

- Viral Inactivation.

  The control on sourcing and collection of bovine tendon and the viral clearance validation study was in compliance with the ISO 22442 standard series.
- Expiration dating / Three-year shelf life.

  Packaging for terminally sterilized medical devices via gamma irradiation and shelf life testing were conducted on device properties, including dimension, thermal stability (DSC), water absorption, moisture content, collagen content and sterility test. The three years of shelf life for product stability and packaging stability has been confirmed by real-time aging.

8. Conclusion

HealiAid Dental is identical with the reference device in composition and manufacturing process, and is substantially equivalent to the predicate devices with respect to technical characteristics, biocompatibility and intended use.

Therefore, HealiAid Dental is substantially equivalent to the predicate devices and reference device.