February 16, 2024

Beijing Biosis Healing Biological Technology Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co, Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K231513
Trade/Device Name: Oral Matrix
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: January 23, 2024
Received: January 23, 2024

Dear Diana Hong:

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)*
K231513

Device Name
Oral Matrix

Indications for Use *(Describe)*
The Oral Matrix is intended for use in extraction sockets only to contain or prevent migration of graft material. The device is supplied sterile and intended for one time use.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K231513

1. Date of Preparation: 2/16/2024

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Subject Device

Trade Name: Oral Matrix

Regulatory Information

Regulation Number: 872.3930
Classification Name: Barrier, Animal Source, Intraoral
Classification: II
Product Code: NPL;
Review Panel: Dental;

Indication for use:
The Oral Matrix is intended for use in extraction sockets only to contain or prevent migration of graft material. The device is supplied sterile and intended for one time use.

Device Description:
The Oral Matrix consists of layered sheets of bioabsorbable extracellular collagen membrane matrix derived from porcine Small Intestinal Submucosa (SIS). These sheets are freeze-dried, packaged in a Tyvek pouch, and sterilized using ethylene oxide to achieve a SAL of 10^{-6}.

The Oral Matrix is available in eighteen different models, the differences between the models are shown in the table below.

Model	Size (cm)	Tolerance	Thickness
SIS-ORP-4L-1×1	1×1	±0.2cm	0.05~0.13mm
SIS-ORP-4L-2×2	2×2		
SIS-ORP-4L-2×3	2×3		
SIS-ORP-4L-3×3	3×3		
SIS-ORP-4L-4×3	4×3		
SIS-ORP-4L-6×6	6×6		
SIS-ORP-4L-1.5×1.5	1.5×1.5		
SIS-ORP-4L-3×5	3×5		
SIS-ORP-4L-2.5×1.5	2.5×1.5		
SIS-ORP-4L-5×4	5×4		
SIS-ORP-4L-4×6	4×6		
SIS-ORP-4L-7×7	7×7		
SIS-ORP-4L-3×3.5	3×3.5		
SIS-ORP-4L-3×7	3×7		

SIS-ORP-4L-4×4	4×4		
SIS-ORP-4L-5×5	5×5		
SIS-ORP-4L-6×8	6×8		
SIS-ORP-4L-8×8	8×8		

5. Identification of Predicate Device

510(k) Number: K161762
Product Name: Dynamatrix/dynamatrix Plus

6. Non-Clinical Test Conclusion

Following non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

Product performance comparison testing
Comparison test has been conducted on the subject device and predicate device, including Burst Strength, Suture Retention Strength, Tensile Strength, Physical Performance, The test results demonstrate the subject device has the similar product performance as those of the predicate device.

Product composition comparison testing
The total protein content, total sugar content, lipid content testing, DNA Residue and peroxyacetic Acid Residue were conducted on the subject device and predicate device. The test results demonstrate the subject device has the similar product composition as those of the predicate device.

Virus Inactivation
In order to demonstrate that the sum of the log clearance of DNA and RNA virus from the virus inactivation processes is at least 6 logs greater than the concentration of virus anticipated in the unprocessed source animal, the sponsor conducted virus inactivation validation according to o ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents. The test results demonstrate that the virus inactivation processes of the subject device reduce more than 6 logs virus.

Package integrity testing
The package integrity test of the sterility maintenance package was conducted according to ASTM F88/F88M-15, ASTM F1886 and ASTM F1929-15. It include: Flexible Packaging by Visual Inspection; seal strength, which shall no less than 1.5N/15mm, and dye penetration, which shall no dye penetration cross the package. The test results demonstrate the sterility maintenance package of the subject device meets the requirements of standards and thus provides sterility maintenance for the finished device.

Shelf life testing

In order to ensure the safety and effectiveness of the subject device in the shelf life, package integrity and product performance testing was conducted on the real-time aged device. The test results demonstrate the subject device can claim 24 month as shelf life.

Biocompatibility testing

The following biocompatibility testing was conducted and the test results demonstrate there are no negative impacts from the materials that are used in the subject device.

Cytotoxicity (ISO 10993-5),
Sensitization (ISO 10993-10),
Intracutaneous reactivity (ISO 10993-23),
Acute systemic toxicity (ISO 10993-11),
Pyrogen (ISO 10993-11),
Implantation (ISO 10993-6),
Subchronic systemic toxicity (ISO 10993-11),
Bacterial reverse mutation test (ISO 10993-3),
Mouse lymphoma TK assay (ISO 10993-3),
Hemolysis study (ASTM F756),
Complement activation (ISO 10993-4),
Partial thromboplastin time (ISO 10993-4),
Chronic system toxicity (ISO 10993-11)
Chemical Characterization (ISO 10993-18, ISO 10993-17).

Animal study

The animal study was performed on a canine model to evaluate the performance and safety by comparing with the predicate device. The results demonstrated that the subject device has ability to preserve the teeth extraction socket compared with predicate device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Subject Device	Predicate Device K161762	Remark
Product code	NPL	NPL	Same
Class	Class II	Class II	Same

Indication for Use	The Oral Matrix is intended for use in extraction sockets only to contain or prevent migration of graft material. The device is supplied sterile and intended for one time use.	DynaMatrix is intended for use in guided tissue regeneration and bone regeneration procedures. It may be used for bone regeneration and healing of periodontal defects, for gingival augmentation, to maintain or enhance alveolar ridges, or to contain or prevent migration of graft material. The device is supplied sterile and intended for one-time use.	Different
Sterile	Yes	Yes	Same
Sterilization method	EO	EO	Same
Single use	Yes	Yes	Same
Material	Porcine small intestinal submucosa	Porcine small intestinal submucosa; primarily collagen types I and III	Same
Drying method	Freeze-dried extracellular matrix	Freeze-dried extracellular matrix	Same
Absorbable	Yes	Yes	Same
Intended for Prescription use only?	Yes	Yes	Same
Target population	Human, oral, periodontal	Human, oral, periodontal	Same
Location of intended application	Setting appropriate for oral surgery	Setting appropriate for oral surgery	Same
Packaging configuration	Tyvek Pouch	Tyvek Pouch	Same
Sizes	1 cm^2 to 64 cm^2 (From 1cm×1cm to 8cm×8cm)	2 cm^2 to 12 cm^2	Different
Thickness (mm)	0.05mm~0.13mm	0.05mm~0.13mm	Same
Biocompatibility	No Cytotoxicity	Comply with ISO 10993 series standards	
	No Sensitization		
	No Intracutaneous Reactivity		
	No Acute Systemic Toxicity		
	Non-irritant after		

	Implantation		
	No Subchronic Systemic Toxicity		
	No Bacterial Reverse Mutation		
	No mutagenic to mouse lymphoma cell		
	No Hemolysis		
	Pyrogen meet the acceptable USP limits.		
	No Complement Activation		
	No Partial Thromboplastin		
	No Chronic System Toxicity		
	No unacceptable risks associated with the extract based on the chemical characterization evaluation		

Different-Indications for Use

The indications for use of subject device is covered by the indications for use of the predicate device. Based on the animal study, the results demonstrated that the subject device has ability to preserve the teeth extraction socket compared with the blank control group and it was similar compared with the predicate device. Therefore, this item is considered substantial equivalent.

Different- Sizes

The size of the subject device is different from the predicate device. However, the test results of product performance comparison testing (burst strength, suture retention strength, tensile strength and physical performance) and product composition comparison testing(total protein content, total sugar content and lipid content, DNA residue and peroxyacetic acid residue) show the performance and composition of the subject device and predicate device have no statistical difference. Therefore, the difference will not affect the safety and effectiveness of the subject device.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantially equivalent to the legally marketed predicate device K161762.