DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 13, 2017

Cook Biotech Incorporated
Perry Guinn
VP Regulatory Affairs And Quality Assurance
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K161762
Trade/Device Name: Dynamatrix/dynamatrix Plus
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: June 24, 2016
Received: June 27, 2016

Dear Perry Guinn:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161762

Device Name
DynaMatrix/DynaMatrix Plus

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY

Submitted by: Perry Guinn, Vice President, Quality Assurance and Regulatory Affairs
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
24 June, 2016

Name of Device:

Trade/Proprietary Names:	DynaMatrix™, DynaMatrix Plus™
Common/Usual Names:	Barrier, animal source, intraoral
Proposed Classification Name:	Bone Grafting Material
Product Code:	NPL
Device Class:	21 CFR §872.3930, Class II

Performance Standards: No performance standards that have been established under Section 514 of the Food, Drug and Cosmetic Act apply to this device.

Predicate Device:
The predicate device is DynaMatrix (K082058), cleared October 2, 2008.

Reference Device:
The reference device is Surgisis Periodontal Membrane (K010952), cleared June 10, 2002.

Intended 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 provided sterile and is intended for one-time use.

This intended use is identical to that of the predicate device cleared under K082058.

Device Description:

DynaMatrix consists of layered sheets of bioabsorbable extracellular collagen membrane matrix derived from porcine Small Intestinal Submucosa (SIS). These sheets are lyophilized, packaged in a Tyvek pouch, and sterilized using ethylene oxide to an SAL of 10^{-6}. The device is available in sheets ranging from 2 cm^2 to 12 cm^2, and can be trimmed or shaped to the appropriate size to

fit the defect to be treated. When hydrated, the membrane maintains suture tear resistance. It is considered to be a permanent contact implanted device, and is fully biocompatible.

DynaMatrix is available by prescription only and is intended for use in an oral surgery setting for 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. Dynamatrix achieves its intended use by providing a passive, resorbable scaffold to guide epithelial tissue ingrowth and angiogenesis of the epithelial layer in order to maintain space around the bony defect, prevent epithelial down-growth, and allow for new bone formation.

Comparison to Predicate Device:
This Special 510(k) describes a dimensional change to supply additional DynaMatrix graft sizes (within the cleared size range of the reference device). The indication for use remains identical to that of the predicate device.

The subject device is identical to the predicate with regard to intended use, indications for use, target population, anatomical site, use setting, performance, materials, compatibility with the environment and other devices, chemical safety, design, standards met, biocompatibility, and sterility. The subject differs from the predicate device solely in regard to its dimension as detailed in the Substantial Equivalence Table (Table 5-1). The introduction of new device sizes does not affect the intended use or the substantial equivalence of the product.

Summary of Non-Clinical Tests:
No additional testing was required.

Substantial Equivalence:
Table 5-1 below provides a comparison of the subject device, its predicate and the reference device.

Table 5-1. Substantial Equivalence Information

Device	DynaMatrix/ DynaMatrix Plus (Subject Device)	DynaMatrix (Predicate Device)	SURGISIS Periodontal Membrane (Reference Device)
Manufacturer	Cook Biotech Inc.	Cook Biotech Inc.	Cook Biotech Inc.
510(k) number	unassigned	K082058	K010952
Product Code	NPL	NPL	NPL
Material composition	Porcine small intestinal submucosa; primarily collagen types I and III	Porcine small intestinal submucosa; primarily collagen types I and III	Porcine small intestinal submucosa; primarily collagen types I and III
Supplied sterile?	Yes		
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Intended for single use?	Yes	Yes	Yes

Device	DynaMatrix/ DynaMatrix Plus (Subject Device)	DynaMatrix (Predicate Device)	SURGISIS Periodontal Membrane (Reference Device)
Intended for prescription use only?	Yes	Yes	Yes
Target population	Human, oral, periodontal	Human, oral, periodontal	Human, oral, periodontal
Location of intended application	Setting appropriate for oral surgery	Setting appropriate for oral surgery	Setting appropriate for oral surgery
Frequency and duration of use	Device is intended to be implanted once and remain in the body until resorbed (implant with contact >30 days)	Device is intended to be implanted once and remain in the body until resorbed (implant with contact >30 days)	Device is intended to be implanted once and remain in the body until resorbed (implant with contact >30 days)
Materials required for use	No additional materials are required	No additional materials are required	No additional materials are required
Packaging configuration	Tyvek® Pouch	Tyvek® Pouch	Tyvek® Pouch
Shelf life	18 months	18 months	18 months
Intended 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.	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.	SURGISIS® Periodontal Membrane is a bioabsorbable, implantable material intended to aid in the treatment of periodontal defects.
Sizes	2 cm^2 to 12 cm^2	1.5 cm x 2.0 cm (3 cm^2) 2.0 cm x 3.0 cm (6 cm^2) 3.0 cm x 4.0 cm (12 cm^2) (3 cm^2 to 12 cm^2)	0.5 cm^2 to 50 cm^2
Thickness (µm)	100-800 (nominal)	100-300 (nominal)	100-800 (nominal)
Resorption profile (Fully resorbed within)	DynaMatrix: 16 weeks DynaMatrix Plus: 26 weeks	16 weeks	16 weeks

Discussion of Similarities and Differences:

The subject device (DynaMatrix/DynaMatrix Plus) has been compared to the predicate device (DynaMatrix, K082058) on the bases of fundamental scientific technology and intended use. The intended use and material composition of both subject and predicate devices are identical. The sole difference is the addition of new sizes to the product line. Any potential new risks associated with the additional device sizes have been identified by appropriate risk analysis methods. These potential new risks have been addressed with verification and validation activities in a manner

satisfactory to pre-determined acceptance criteria to ensure that no change to device substantial equivalence has occurred. Specifically, biocompatibility qualification verification was performed to ensure that no new risks of biocompatibility were present. Validation activities were comprised of a swine pilot study that showed successful incorporation and no foreign body response for devices matching the nominal thickness of the subject device, and FDA clearance of another SIS device with the same nominal thickness (K133306).

Conclusion:

Successful risk analysis and completion of verification and validation activities provide evidence to support the conclusion that the size modification does not introduce new risks and that the subject device performs comparably and is substantially equivalent to the predicate device that is currently marketed for the same intended use.