DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 28, 2016

Cook Biotech Incorporated
Nick Wang, Ph.D.
Regulatory Affairs Scientist
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K160136
Trade/Device Name: Flowable Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 2, 2016
Received: September 6, 2016

Dear Dr. Wang:

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 yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K160136

Device Name
Flowable Wound Matrix

Indications for Use *(Describe)*
The Flowable Wound Matrix is intended for the management of wounds including:

- partial and full-thickness wounds,
- pressure ulcers,
- venous ulcers,
- diabetic ulcers,
- chronic vascular ulcers,
- tunneled/undermined wounds,
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),
- trauma wounds (abrasions, lacerations, 2nd degree burns, skin tears),
- draining 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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510(k) Summary

Submitted By: Perry W. Guinn
Vice President of Quality Assurance & Regulatory Affairs
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
23 September 2016

Name of Device:

Trade/Proprietary Name:	Flowable Wound Matrix
510(k) Number:	K160136
Common/Usual Name:	Dressing, Wound, Collagen
Classification Name:	Dressing, Wound, Collagen
Product Code:	KGN
Device Class:	The product code KGN is considered by FDA to be unclassified.

Predicate Device:

Oasis Wound Matrix (K061711)

Reference Devices:

Integra Flowable Wound Matrix (K072113)
Cook ECM Powder (K152033)
MicroMatrix (K153754)

Intended Use:

The Flowable Wound Matrix is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, 2nd degree burns, skin tears) and draining wounds.

Device Description:

The Flowable Wound Matrix is a wound management device consisting of particulate Porcine Small Intestinal Submucosa (SIS) and fructose, a natural carrier. The device is an addition to the family of SIS-based wound management devices (Oasis Wound Matrix (K061711) and Cook ECM Powder (K152033)) already manufactured by Cook Biotech

Incorporated. The device is supplied dry, rehydrated with saline at the time of application, and delivered topically to the wound through a pre-supplied syringe. SIS, which composes the majority of the device, is the same base material as that of the predicate device Oasis Wound Matrix (K061711) and reference device Cook ECM Powder (K152033). In addition to SIS, the device also contains fructose, a carrier added only to facilitate the preparation and delivery of the device. Fructose is a sugar naturally found in the body and is readily metabolized. The Flowable Wound Matrix is meant to be employed by the user to manage wounds of the types outlined in the intended use of the device. The device achieves its intended use by providing a scaffold for cellular invasion and capillary growth, and maintaining a supportive environment for wound management.

Comparison to Predicate Device:

The subject and predicate devices share the same fundamental technology; the main components of both devices are porcine SIS. The main difference between the subject and predicate is the device configuration and method of application. The Oasis Wound Matrix is supplied as a dry sheet of SIS and is applied topically by rehydrating and placing the sheet directly onto a wound. The Flowable Wound Matrix, in contrast, is particulate SIS supplied dry in a cylindrical shape. Upon rehydration with saline, the device acquires a gel-like consistency and can be applied directly to the wound site using the supplied syringe.

Summary of Non-Clinical Tests:

The following testing was performed to demonstrate substantial equivalence:

- Biocompatibility Testing:
  - Cytotoxicity
  - Sensitization
  - Irritation/Intracutaneous Reactivity
  - Acute Systemic Toxicity

- Other Testing:
  - Rehydration and Deployment
  - Package Integrity
  - Shelf Life
  - Collagen Characterization (Western Blot and Digital Scanning Calorimetry)

Substantial Equivalence:

Table 5-1 provides a comparison of the subject and predicate devices.

To provide further evidence of substantial equivalence, CBI used the 510(k) Decision-Making Flowchart from the FDA guidance document *Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (July 28, 2014)* to compare and assess the intended use and the technological characteristics of the subject and predicate devices. Specifically, the intended uses of both devices are identical. In terms of technological characteristics, while the subject device differs from the predicate device in form (sheet vs. flowable), both devices share the same underlying technology, namely topical application of porcine SIS for wound management. In this 510(k), CBI submits biocompatibility, deployment, package and shelf-life testing as evidence to demonstrate the device can function as intended and performs comparably to the predicate device that is currently marketed for the same intended use. In conclusion, CBI believes the Flowable Wound Matrix is substantially equivalent to the Oasis Wound Matrix based on success in non-clinical testing and the identical nature of the fundamental technology and intended use.

Table 5-1. Substantial Equivalence Information

	Flowable Wound Matrix (Subject Device)	Oasis® Wound Matrix (Predicate Device)	Integra™ Flowable Wound Matrix (Reference Device)	Cook ECM Powder (Reference Device)	MicroMatrix (Reference Device)
510(k) number	K160136	K061711	K072113	K152033	K153754
Indication for Use	The Flowable Wound Matrix is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), draining wounds.	Oasis® Wound Matrix is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), draining wounds.	Integra™ Flowable Wound Matrix is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), draining wounds.	Cook® ECM Powder is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), draining wounds.	MicroMatrix® is intended for the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunnel/undermined wounds, surgical wounds (donor sites/ grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds.
Collagen Source	Porcine small intestinal submucosa	Porcine small intestinal submucosa	Bovine tendon collagen	Porcine small intestinal submucosa	Porcine urinary bladder matrix

	Flowable Wound Matrix (Subject Device)	Oasis® Wound Matrix (Predicate Device)	Integra™ Flowable Wound Matrix (Reference Device)	Cook ECM Powder (Reference Device)	MicroMatrix (Reference Device)
Dimensions	Particles of ≤1000 µm in diameter Volume of device is 1.25cc	2 cm x 2 cm to 20 cm by 40 cm	Collagen Particles of 200 – 2000 µm in diameter* Volume of device is 3cc	Particles of ≤1000 µm in diameter	Two particle distributions, particles of <500 µm and <1000 µm
Technological Features	Device is rehydrated to a gel-like consistency using saline in a dual syringe/luer connector system, and then applied topically.	Sheet is rehydrated and applied topically	Device is rehydrated to a gel-like consistency using saline in a dual syringe/luer connector system, and then applied topically.	Powder, applied directly topically	Particle, applied directly topically
Supplied sterile?	Yes	Yes	Yes	Yes	Yes
Sterilization method	E-beam	Ethylene Oxide	Unknown	Ethylene Oxide	E-beam
Intended for single use?	Yes	Yes	Yes	Yes	Yes