DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 28, 2015

Cook Biotech Incorporated
Dr. Katie Molland
Regulatory Affairs
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K152033
Trade/Device Name: Cook® ECM Powder
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 21, 2015
Received: July 22, 2015

Dear Dr. Molland:

This letter corrects our letter of August 19, 2015.

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" (21CFR 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)*
K152033

Device Name
Cook® ECM Powder

Indications for Use *(Describe)*
Indications For Use: 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

The device is provided 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

Submitted by: Perry Guinn, Vice President, Quality Assurance and Regulatory Affairs
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
21 July, 2015

Name of Device:

Trade Name:	Cook® ECM Powder
Common/Usual name:	Collagen Wound Dressing
Proposed classification name:	Dressing, Wound, Collagen
Product Code:	KGN
Device Class:	The product code KGN is considered by FDA to be unclassified.

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 for Cook® ECM Powder is Oasis® Wound Matrix manufactured by Cook Biotech Incorporated (510(k) No. K061711) cleared on July 19, 2006.

Reference Device:
The reference device for this submission is ACell™ Powdered Wound Dressing (510(k) No. K060888) cleared on June 23, 2006.

Intended Use:
The intended use of Cook® ECM Powder is 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

The device is supplied sterile and is intended for one-time use.

This intended use is identical to that previously cleared under K061711 for the predicate device.

Device Description:
Cook® ECM Powder is composed of porcine small intestinal submucosa (SIS) that has been processed to isolate the extracellular matrix (ECM), or medical-grade SIS. Further treatment and final sterilization yields a powdered device prepared for management of wounds. The powder 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 modification made to Oasis® Wound Matrix to produce Cook® ECM Powder can be defined as a change in device size. Like Cook® ECM Powder, Oasis® Wound Matrix is composed of medical-grade SIS. Both devices have the same intended use, however, the predicate device is a flat sheet of SIS, while the subject device is a flat sheet that has been cryomilled into a powder.

Comparison to Reference Device:
ACell™ Powdered Wound Dressing is another product indicated for wound healing that is manufactured from porcine tissue; in this case urinary bladder matrix (UBM). UBM is also a three-dimensional, acellular, collagen-rich extracellular membrane. It is included in this submission as a reference device in order to highlight a common technological characteristic - both the subject and reference devices are powdered forms of extracellular matrix sheets (Oasis® Wound Matrix and ACell™ UBM Lyophilized Wound Dressing, respectively) that are intended to aid in wound management.

Summary of Non-Clinical Tests:
The following testing was performed to mitigate new risks posed by the size change and to demonstrate substantial equivalence to the predicate device:

- Biocompatibility Testing:
  - Cytotoxicity
  - Acute systemic toxicity
  - Irritation/Intracutaneous reactivity

- Other Product Testing:
  - Deployability
  - Simulated shipping, handling, and storage followed by visual inspection and testing of seal strength and integrity
  - Heavy metal quantification
  - Particle size characterization

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

Conclusion:
In summary, the subject device, Cook® ECM Powder, has been compared to the predicate device, Oasis® Wound Matrix, on the bases of fundamental scientific technology and intended use. Oasis® Wound Matrix is an FDA-cleared device of long standing (K973170/K061711). The intended uses of both subject and predicate devices are identical. Furthermore, the devices share a common basic material, SIS. The safety of SIS, both in Oasis® Wound Matrix and other Cook Biotech Inc. products, has been established via biocompatibility testing as well as a significant history of successful treatment throughout the body in a wide variety of applications on or in nearly one million human patients. Any potential new risks associated with the change in shape of the predicate device from sheet to powder form have been identified by appropriate risk analysis techniques. These potential new risks have been addressed with verification and validation activities in a manner satisfactory to the pre-determined acceptance criteria to ensure that no change to device safety has occurred. Based on comparison of fundamental scientific technology and intended use and following completion of verification and validation testing, it is the position of CBI that Cook® ECM Powder is substantially equivalent to Oasis® Wound Matrix and the technological differences between subject and predicate devices do not raise new questions of safety or effectiveness.

Table 5-1. Substantial Equivalence Information

Device	Cook® ECM Powder (Subject Device)	Oasis® Wound Matrix (Predicate Device)
Manufacturer	Cook Biotech Inc.	Cook Biotech Inc.
510(k) number	K152033	K061711
Intended Use	The intended use of Cook® ECM Powder is 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.	The intended use of Oasis® Wound Matrix is 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.
Product Code	KGN	KGN
Material	Porcine small intestinal submucosa; primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)	Porcine small intestinal submucosa; primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)
Dimensions	Particles of ≤1000 µm	Sheets of 2 cm x 2 cm to 20 cm x 40 cm
Supplied sterile?	Yes	Yes
Sterilization method	Ethylene Oxide	Ethylene Oxide
Intended for single use?	Yes	Yes