Cook Incorporated
% Mr. Thomas Kardos
Vice-President, Regulatory Affairs
750 Daniels Way, P.O. Box 489
BLOOMINGTON IN 47402

July 17, 2018

Re: K171272
Trade/Device Name: Cook-Swartz Doppler Flow Probe
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: July 12, 2018
Received: July 13, 2018

Dear Mr. Kardos:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171272

Device Name
Cook-Swartz Doppler Flow Probe

Indications for Use *(Describe)*
The Cook-Swartz Doppler Flow Probe is for monitoring blood flow in vessels intraoperatively, and following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

Device: Cook-Swartz Doppler Flow Probe
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)			P				
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)			P				

N = new indication; P = previously cleared by FDA; E = added under this appendix

The Cook-Swartz Doppler Flow Probe is intended for use with the Swartz Doppler Monitoring System for monitoring blood flow in vessels intraoperatively, and following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers.

Prescription Use Only (Part 21 CFR 801 Subpart D)

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2.0 510(k) SUMMARY

Cook-Swartz Doppler Flow Probe
As required by 21 CFR 807.92
Date Prepared: April 27, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Tom Kardos
Email:	RegSubmissions@CookMedical.com
Contact Phone Number:	724-845-8621
Contact Fax Number:	724-845-2848

Device Information:

Trade Name:	Cook-Swartz Doppler Flow Probe
Common Name:	Doppler Probe
Classification Name:	Diagnostic ultrasonic transducer
Regulation:	21 CFR 892.1570
Product Code:	ITX
Device Class:	II
Classification Panel:	Radiology

Predicate Device:

The Cook-Swartz Doppler Flow Probe, is substantially equivalent to the predicate device, the previously-submitted Cook-Swartz Doppler Flow Probe as described in K022649.

Device Description

The Cook-Swartz Doppler Flow Probe contains a piezoelectric crystal transducer assembly at its distal end. The transducer is a 1 mm diameter disc and operates at 20 MHz. The transducer is attached to a silicone cuff (either 5 mm × 32 mm or 5 mm × 17.4 mm) that is designed to be secured around a blood vessel. Proximal to the cuff, braided wires connect the transducer to suture pads and to a proximal polyurethane-covered wire. The polyurethane-covered wire ends in a two-pin plug connector.

The cuff is designed to be wrapped around the vessel to be monitored. The length of the cuff represents the circumference of the vessel that can be covered. The cuff is 5 mm wide regardless of length. The width of the cuff represents the length of the vessel that can be covered with the cuff.

Intended Use

The Cook-Swartz Doppler Flow Probe is for monitoring blood flow in vessels intraoperatively, and following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers.

Comparison to Predicate Device

The Cook-Swartz Doppler Flow Probe is substantially equivalent to the predicate device, the previously-submitted Cook-Swartz Doppler Flow Probe as described in K022649. The table below presents the similarities and differences between the two products for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence and were developed using acceptable scientific methods for evaluation.

	Cook-Swartz Doppler Flow Probe (K022649)	**Cook-Swartz Doppler Flow Probe (Subject of this submission)**
Indications for Use	The Cook-Swartz Doppler Flow Probe is for monitoring blood flow in vessels intraoperatively, and following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers.	Same
Transducer		
Type	Piezoelectric crystal	Same
Signal frequency	20 MHz	Same
Signal amplitude	15 V (peak-to-peak) into 50 Ω	Same
Transmitter pulse width & repetition frequency	0.4 μs; 78.1 KHz	Same
Cuff		
Cuff sizes	27 mm × 25 mm	37 mm (L) × 5 mm (W) 17.4 mm (L) × 5 mm (W)
Material	NuSil MED-4850 silicone	NuSil MED-4750 silicone

	Cook-Swartz Doppler Flow Probe (K022649)	**Cook-Swartz Doppler Flow Probe (Subject of this submission)**
Other patient-contact materials		
Adhesive	NuSil MED-2000 silicone	NuSil MED-1137 silicone
Epoxy	Master Bond Polymer System EP42HT epoxy	Master Bond Polymer System EP42HT epoxy *or* Hysol EE0079 & HD0070 two-part epoxy
Wire	Neoflon NP-101 FEP-coated wire	Same
Suture pads	NuSil MED-4950 or MED-4850 silicone	NuSil MED-4050 Silicone
Other characteristics		
Sterilization	Ethylene oxide	Same
Compatible Monitor	Cook Model DP-M350	Same

Technological Characteristics

The transducer, electrical components, and the polyurethane-covered wires and connector of the Cook-Swartz Doppler Flow Probe are unchanged compared to the predicate device; therefore, it was not necessary to retest acoustic and electrical characteristics of the device.

A biocompatibility assessment was made, including assessment of the following biological effects:

1. Cytotoxicity
2. Sensitization
3. Irritation or intracutaneous reactivity
4. Acute systemic toxicity
5. Material-mediated pyrogenicity
6. Subacute/subchronic toxicity
7. Genotoxicity
8. Implantation
9. Chronic toxicity
10. Carcinogenicity

The assessment concluded that the materials of the device provide a reasonable assurance of safety with respect to biocompatibility.

The following tests were conducted and demonstrate the effective performance of the device:

- Cuff detachment force
- Suture pad attachment force

Conclusion

The results of these tests support the conclusion that the Cook-Swartz Doppler Flow Probe performs acceptably and does not raise new questions of safety and effectiveness, thus supporting a determination of substantial equivalence.