December 12, 2019

Cook Incorporated
David Lehr
Regulatory Affairs Team Lead
750 Daniels Way
Bloomington, Indiana 47404

Re: K191163
Trade/Device Name: Lumax Guiding Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 15, 2019
Received: November 18, 2019

Dear David Lehr:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191163

Device Name
Lumax® Guiding Catheters

Indications for Use *(Describe)*
Intended for the intravascular introduction of interventional devices into the peripheral, including pulmonary, vasculature.

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.

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K191163

510(k) Summary

As required by 21 CFR §807.92
Date Prepared: November 27, 2019

Submitted By:

Applicant:	Cook Incorporated
Contact:	David Lehr, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102309
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Device Information:

Trade Name:	Lumax® Guiding Catheters
Common Name:	Percutaneous catheter
Classification Panel:	Cardiovascular
Regulation:	21 CFR §870.1250
Product Code:	DQY

Predicate Devices:

ConcierGE® Guiding Catheter (K132409), manufactured by Merit Medical.

Device Description:

Lumax® Guiding Catheters are conduits introduced, either singly or as a coaxial pair, into a vein or artery and tracked over a wire guide to the site of a vascular lesion where interventional devices can be delivered through the guiding catheter's internal lumen for treatment. The Lumax® Guiding Catheters may include either a single guiding catheter or a coaxial catheter pair (composed of an outer guiding catheter and an inner coaxial catheter). The single guiding catheters are available in a 7.0 French outer diameter in lengths of 80 or 90 cm. They are manufactured with a multilayered braided nylon shaft, bonded Luer hub, and radiopaque tip. The guiding catheters are designed with a multipurpose (MPA) distal curve configuration. The coaxial catheter pair comprises an outer guiding catheter matched to an inner coaxial catheter. The guiding catheter component is available in an outer diameter of 8.0 French and a length of 80 cm. The inner coaxial catheter is manufactured from radiopaque braided nylon tubing and has an outer diameter of 6.0 French and a length of 100 cm. For lubricity, the distal 40 cm of the

inner catheter is treated with hydrophilic coating. The Lumax® Guiding Catheters are supplied as packaged, sterile devices, intended for single-patient use.

Intended Use:

Intended for the intravascular introduction of interventional devices into the peripheral, including pulmonary, vasculature.

Comparison of Technological Characteristics to Predicate:

The Lumax® Guiding Catheters and the predicate device, the ConcierGE® Guiding Catheter (K132409), manufactured by Merit Medical, are substantially equivalent in that they have similar indications for use, technological characteristics, methods of construction, and principles of operation. The differences between the subject device and the predicate device, including differences in indications for use wording, device dimensions, and device components, were appropriately assessed and do not present any new questions of safety and/or effectiveness. Based on the comparison of the design, indications for use, materials, fundamental technology, and principles of operation, the subject device is considered to be substantially equivalent to the currently marketed predicate device. The substantial equivalence comparison of the subject device to the predicate is provided in the following table.

Substantial Equivalence Comparison Table

	PREDICATE DEVICE	**SUBJECT DEVICE**
	ConcierGE® Guiding Catheter (K132409)	**Lumax® Guiding Catheter**
Manufacturer	Merit Medical	Cook Incorporated
Regulation Number Product Code Classification Name Class	21 CFR §870.1250 DQY Percutaneous catheter II	Identical
Indications for Use	Intended for the intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.	Intended for the intravascular introduction of interventional devices into the peripheral, including pulmonary, vasculature.
Guiding Catheter Materials	Outer layer: Pebax Wire braid: Stainless Steel Inner lining: PTFE Radiopaque tip: Unknown	Outer layer: Nylon Wire braid: Stainless Steel Inner lining: PTFE Tip: Radiopaque Nylon/Tungsten
Guiding Catheter Sizes (Fr)	5, 6, 7, 8	7, 8
Guiding Catheter Lengths (cm)	100	80, 90
Guiding Catheter Tip Configuration	Various, including MP1 (Multipurpose) Curve	MPA (Multipurpose) Curve

Substantial Equivalence Comparison Table (continued)

	PREDICATE DEVICE	SUBJECT DEVICE
	ConcierGE® Guiding Catheter (K132409)	**Lumax® Guiding Catheter**
Inner Catheter Materials	N/A	Shaft: Nylon Hydrophilic Coating (40 cm) Tip: Radiopaque Nylon Adapter: ABS Connector Cap: Acetal
Inner Catheter Size (Fr)		6 Fr
Inner Catheter Length (cm)		100 cm
Packaging	Unknown	Tyvek/Polyethylene-polyester Film
Sterilization (SAL 10^{-6})	EtO	Identical
Shelf Life	3 years	Identical

Technological Characteristics:

The subject device, Lumax® Guiding Catheters, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below.

Biocompatibility Testing – Per ISO 10993-1 and FDA guidance, testing for Cytotoxicity, Genotoxicity, Sensitization, Acute Systemic Toxicity, Intracutaneous Irritation, Material-Mediated Pyrogenicity, Hemocompatibility (Hemolysis, Complement Activation, Partial Thromboplastin Time), and Thrombogenicity were performed on all components of the subject device. All test results met the acceptance criteria, where applicable, or demonstrated that the device is biocompatible.

Performance Testing

- Radiopacity – The radiopacity of the guiding catheter and inner coaxial catheter was tested. The devices were visible, and visibility was qualitatively non-inferior to the user-defined standard.
- Lubricity – The lubricity of the hydrophilic coating on the inner coaxial catheter was evaluated. The acceptance criteria for the comparison of means test and the coated test articles were met.
- Tensile – All bonds and joints were tested for tensile strength in accordance with Annex B of BS EN ISO 10555-1. The predetermined acceptance criteria for the studies were met.
- Stress Cracking – The Luer locks of the subject device were evaluated according to the stress cracking requirements stated in ISO 80369-7. The predetermined acceptance criteria for the study were met.
- Dimensional Verification – The outer diameters of the subject device were evaluated. The predetermined acceptance criteria for the study were met.

- Visual, Dimensional, and Compatibility Verification – The subject device was tested according to internal requirements for compatibility, inner diameter, outer diameter, and effective length verification. Additionally, the subject device was evaluated according to the visual inspection requirements of Section 4.12 of BS EN ISO 10555-1. The predetermined acceptance criteria for the studies were met.
- Air Leakage – The subject device was evaluated according to the air leak requirements of BS EN ISO 10555-1. The predetermined acceptance criterion for the study was met.
- Liquid Leakage – The subject device was evaluated according to the liquid leakage requirements of BS EN ISO 10555-1. The predetermined acceptance criterion for the study was met.
- Simulated Use – The subject device was tested for its ability to perform as intended in expected clinical use conditions. The predetermined acceptance criteria for the study were met.
- Particulate Testing and Coating Integrity – This study successfully characterized the particulate counts and hydrophilic coating integrity of the Lumax® Guiding Catheters.
- Rollback – The guiding catheters were tested for their ability to be inserted through a simulated tissue without signs of rollback of their tips and to meet the requirements listed in Annex A of BS EN ISO 11070. The predetermined acceptance criteria for the study were met.

Conclusion:

The results of these tests support a conclusion that the Lumax® Guiding Catheters, subject of this submission, met the design input requirements based on the device's intended use and that they are substantially equivalent to the predicate device, the ConcierGE® Guiding Catheter (Merit Medical, K132409).