February 15, 2019

Cook Incorporated
Ms. Jennifer Allman, RAC
Regulatory Affairs Project Manager
750 Daniels Way
Bloomington, IN 47402

Re: K181353
Trade/Device Name: Lunderquist® Fixed Core Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 15, 2019
Received: January 15, 2019

Dear Ms. Allman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Lydia S. Glaw -S
Digitally signed by Lydia S. Glaw -S
Date: 2019.02.15 15:30:39 -05'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181353

Device Name
Lunderquist® Fixed Core Wire Guide

Indications for Use *(Describe)*
The Lunderquist Fixed Core Wire Guides are intended to facilitate placement of devices used during diagnostic and interventional procedures.

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

Lunderquist® Fixed Core Wire Guide
21 CFR §807.92
Date Prepared: May 21, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Jennifer L. Allman
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104280
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Lunderquist® Fixed Core Wire Guide
Common Name:	Wire, Guide, Catheter
Classification Name:	Catheter guide wire
Regulation:	21 CFR §870.1330
Product Code:	DQX

Predicate Device:

The predicate device is the Mandril Wire Guides (Cook, Inc., K171997) cleared for market on March 30, 2018.

Reference Device:

The reference device is the Fixed Core Wire Guides (Cook Inc., K171764) cleared for market on March 9, 2018.

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Device Description:

The Lunderquist® Fixed Core Wire Guide, subject of this submission, is a Class II device according to 21 CFR §870.1330; product code DQX (Wire, Guide, Catheter). The subject device consists of a mandril design with a distal spring coil anchored over the distal portion of the mandril and a cannula anchored over the proximal portion of the mandril. The Lunderquist® Fixed Core Wire Guide is available with an outside diameter of 0.038 inch and a length of 120 centimeters (cm). The tip portion of the subject device is straight. The Lunderquist® Fixed Core Wire Guide is a packaged, sterile device intended for single patient use.

Intended Use:

The Lunderquist Fixed Core Wire Guides are intended to facilitate placement of devices used during diagnostic and interventional procedures.

Comparison of Technological Characteristics to Predicate:

The Lunderquist® Fixed Core Wire Guide, subject of this submission, is substantially equivalent to the predicate device, the Mandril Wire Guide (K171997), in that both devices have identical indications for use. The subject device is similar in technological characteristics (i.e., design and materials) to the predicate device with the addition of a 0.038 inch diameter configuration and a proximal cannula design.

Performance Data:

The following tests were performed to demonstrate that the Lunderquist® Fixed Core Wire Guide met applicable design and performance requirements and support a determination of substantial equivalence.

- Biocompatibility Testing – Tested in accordance with ISO 10993-1:2009. The pre-determined acceptance criteria were met.
- Corrosion Testing – Tested in accordance with Annex B of ISO 11070:2014. The pre-determined acceptance criteria were met.
- Flexing Test – Tested in accordance with the Annex G of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Surface Examination – Tested in accordance with BS EN ISO 11070:2014 Section 4.3. The pre-determined acceptance criteria were met.
- Fracture Testing – Tested in accordance with Annex F of BS EN ISO 11070:2014. The pre-determined acceptance criteria were met.
- Tensile Testing – Tested in accordance with the applicable values of BS EN ISO 11070:2014, Annex H. The pre-determined acceptance criteria were met.

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- Tip Flexibility Testing (Tip Deflection) – Tested in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995). The pre-determined acceptance criteria were met.
- Radiopacity Testing – Tested in accordance with ASTM F640-12. The pre-determined acceptance criteria were met.
- Dimensional Measurement and Catheter Compatibility Testing – Tested in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995) and with an approved study protocol. The pre-determined acceptance criteria were met.

Conclusion:

The results of these tests support a conclusion that the Lunderquist® Fixed Core Wire Guide, subject of this submission, met the design input requirements based on the device's intended use and support the conclusion this device does not raise new questions of safety and/or effectiveness. The results of these tests support a determination of substantial equivalence to the predicate device, the Mandril Wire Guides (K171997).