February 17, 2022

William Cook Europe ApS
Jennifer Brown
Director, Global Regulatory Science-Vascular/Regulatory Affairs
Sandet 6
Bjaeverskov, 4632
Denmark

Re: K220137
Trade/Device Name: Lunderquist Extra Stiff Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 14, 2022
Received: January 18, 2022

Dear Jennifer Brown:

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,

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220137

Device Name
Lunderquist Extra Stiff Wire Guides

Indications for Use *(Describe)*
The Lunderquist Extra Stiff Wire Guides are intended to facilitate catherization and/or placement of devices during vascular diagnostic procedures and vascular interventional procedures. The Lunderquist Extra Stiff Wire Guides are intended for use in the major vessels, the aorta and vena cava, including their access vessels and adjacent vessels.

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.

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510(k) Summary
K220137

Date Prepared:	14 January 2022
Submitted By:	William Cook Europe ApS
	Sandet 6
	4632 Bjaeverskov, Denmark
Contact:	Mie Dyrholm
Phone:	+45 56 86 84 92
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Device:

Trade Name:	Lunderquist® Extra Stiff Wire Guides
Common Name:	Catheter Guide Wire / Wire, Guide, Catheter
Classification Name:	Catheter Guide Wire
Regulation / Product Code:	21 CFR 870.1330 / DQX
Classification / Panel:	Class II / Cardiovascular

Intended Use:

The Lunderquist Extra Stiff Wire Guides are intended to facilitate catherization and/or placement of devices during vascular diagnostic procedures and vascular interventional procedures. The Lunderquist Extra Stiff Wire Guides are intended for use in the major vessels, the aorta and vena cava, including their access vessels and adjacent vessels.

Predicate Devices:

The subject devices are substantially equivalent to the predicate devices, the Lunderquist® Extra Stiff Wire Guides (K171513, cleared 07 December 2017).

Comparison to Predicate Device:

The subject Lunderquist® Extra Stiff Wire Guides are substantially equivalent to the predicate Lunderquist® Extra Stiff Wire Guides (K171513). The subject devices are identical to the predicate devices in terms of principles of operation, design, materials of construction, manufacturing processes, sterilization process, and basic technological characteristics. The purpose of this submission is to clarify the intended use statement and update device labeling based on post-market surveillance information.

Device Description:

Straight (TSMG-/-LES) and Curved (TSCMG-/-LES) Lunderquist® Extra Stiff Wire Guide. PTFE-coated stainless steel wire guides with lengths ranging from 90 cm to 300 cm and either a 4 cm or 7 cm flexible tip. For the 260 cm and 300 cm lengths, the flexible tip includes an inner gold coil for enhanced visibility. The J-curve radius for the curved wire guides is either 3 mm or 7 mm.

Double curved (TSCMG-/-LESDC) and extended double curved (TSCMG-/-E-LESDC) Lunderquist® Extra Stiff DC Wire Guide. PTFE-coated stainless steel wire guides with a 4 cm flexible tip that includes an inner gold coil for enhanced visibility. TSCMG-/-LESDC has a primary/secondary curve radius on 75/15 mm, and TSCMG-/-E-LESDC has an extended primary/secondary curve radius on 55/15 mm.

The Lunderquist® Extra Stiff Wire Guide is used both to assist in anatomical access for other devices (not included) and to support the delivery of medical devices. The wire guide is introduced into the target vessel; other devices, such as a sheath, catheter, stent, or endovascular graft can then be passed over the wire guide to be positioned or manipulated within the vascular system.

The Lunderquist® Extra Stiff Wire Guides are available in different lengths, shapes, etc. to accommodate different anatomical applications.

Performance Testing:

No changes to the design, materials, manufacturing, sterilization, or principles of operation have been introduced with the subject devices. Therefore, performance testing was not warranted, and testing provided for the predicate device (K171513) remains applicable.

Conclusion:

The Lunderquist® Extra Stiff Wire Guides are substantially equivalent to the predicate devices, the Lunderquist® Extra Stiff Wire Guides (K171513). No changes have been made to the wire guides. The only changes being made are to the device IFU.