December 7, 2017

William Cook Europe ApS
Henriette Christiansen
Director of Regulatory Affairs
Sandet 6
DK-4632 Bjaeverskov, Denmark

Re: K171513
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: November 3, 2017
Received: November 7, 2017

Dear Henriette Christiansen:

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 and Part 809); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*
K171513

Device Name
Lunderquist Extra Stiff Wire Guide

Indications for Use *(Describe)*
The device is intended for complex diagnostic and interventional procedures where increased body, flexibility, and low surface friction of the wire guide is needed.

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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*"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."*

# 5.0 510(k) SUMMARY

**Lunderquist Extra Stiff Wire Guide**
**21 CFR § 870.1330**
**Date Prepared: May 23, 2017**

**Submitted By:**


| | |
|---|---|
| Applicant: | William Cook Europe ApS |
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| Contact Phone Number: | +45 56 86 88 59 |
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**Device Information:**

| | |
|---|---|
| Trade Name: | Lunderquist® Extra Stiff Wire Guide |
| Common Name: | Catheter Guide Wire / Wire, Guide, Catheter |
| Classification Name: | Catheter Guide Wire |
| Proposed Classification: | 870.1330 DQX Class II, Cardiovascular |

**Predicate Devices:**

The Lunderquist Extra Stiff Wire Guide and Lunderquist Extra Stiff DC Wire Guide (William Cook Europe ApS, K061670) were cleared for market on January 19, 2007. The predicate devices are PTFE-coated stainless steel wire guides with an outer diameter of 0.035 inches and lengths of 90 cm to 300 cm. For lengths 260-300 cm, a radiopaque gold coil is present on the flexible distal tip. The Lunderquist Extra Stiff DC Wire Guide features a double curved tip design. The predicate devices are intended for complex diagnostic and interventional procedures where increased body, flexibility, and low surface friction of the wire guide is needed.

**Description of the Subject Device:**

The subject device, the Lunderquist Extra Stiff DC Wire Guide with an extended double curved tip, is considered a line extension of the predicate Lunderquist Extra

Stiff DC Wire Guides. The subject device is a PTFE-coated 0.035 inch stainless steel wire with a 4 cm flexible tip that includes an inner gold coil for enhanced visibility. The length of the device is either 260 cm or 300 cm and the J-curve radius is 15 mm. The devices have the body and stiffness required to control large diameter, stiff devices without causing damage to the patient's anatomy or the lumen of the delivery system.

**Indications for Use:**
The device is intended for complex diagnostic and interventional procedures where increased body, flexibility, and low surface friction of the wire guide is needed.

**Comparison to Predicate Devices:**
The Lunderquist Extra Stiff DC Wire Guide - Extended Double Curved, subject of this submission, is substantially equivalent to the predicate devices, the Lunderquist Extra Stiff Wire Guide and the Lunderquist Extra Stiff DC Wire Guide (K061670) in that these devices all belong to the same product family. As such, the Lunderquist Extra Stiff DC Wire Guide – Extended Double Curved is similar in design, technological characteristics, materials, and intended use to the cleared Lunderquist Extra Stiff Wire Guides. The characteristic differences between the subject device and the predicate devices include a modified double curved configuration and a PTFE coating reformulation.

**Performance data:**
The following tests were performed to demonstrate that the Lunderquist Extra Stiff DC Wire Guide - Extended Double Curved 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.
- Surface test – Tested in accordance with EN ISO 11070. The pre-determined acceptance criteria were met.
- Tape adhesion test – Evaluation of PTFE coating adhesion. The pre-determined acceptance criteria were met.
- Friction test – Evaluation of device performance. The pre-determined acceptance criteria were met.
- Flexing test - Tested in accordance with EN ISO 11070. The pre-determined acceptance criteria were met.

- Peak tensile force - Tested in accordance with EN ISO 11070. The pre-determined acceptance criteria were met.
- Ultrasound test – Evaluation of PTFE coating adhesion. The pre-determined acceptance criteria were met.
- Simulated Use Test – Evaluation of device performance in a bench top model under conditions intended to simulate use. The pre-determined acceptance criteria were met.
- Torque test – Evaluation of device performance. The pre-determined acceptance criteria were met.

**Conclusion:**

In summary, the Lunderquist Extra Stiff DC Wire Guide - Extended Double Curved, described in this submission, met the design input requirements based on the intended use and supports the conclusion that this device does not raise new questions of safety and effectiveness. The results of these tests support a determination of substantial equivalence to the predicate devices, the Lunderquist Extra Stiff Wire Guide and Lunderquist Extra Stiff DC Wire Guide (K061670).