November 9, 2025

Anette Hulstrom
Specialist, Submissions, Regulatory Affairs
William Cook Europe ApS
Sandet 6
Bjaeverskov, 4632
Denmark

Re: K251596
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: October 8, 2025
Received: October 10, 2025

Dear Anette Hulstrom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.11.09 11:46:24 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251596

Device Name
Lunderquist Extra Stiff Wire Guide

Indications for Use *(Describe)*
The Lunderquist Extra Stiff Wire Guides are intended to facilitate catheterization and/or placement of devices during vascular interventional procedures.
The Lunderquist Extra Stiff Wire Guides are intended for use in the aorta, including its access vessels and major adjacent vessels.
The Lunderquist Extra Stiff Wire Guides are auxiliary devices and hence not primary interventional devices themselves. Instead, they are intended to facilitate vascular access and/or delivery of over-the-wire medical devices during endovascular procedures, including TEVAR/EVAR procedures.
The Lunderquist Extra Stiff Wire Guides are both long and stiff; features that make them suitable for facilitating endovascular procedures that involve placement of large devices e.g., stent grafts in the aorta. The wire guides are not intended for coronary or neurovascular use.

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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Special 510(k) Summary: K251596

Lunderquist Extra Stiff Wire Guide

Date prepared:	13 May 2025
Submitted By	William Cook Europe ApS Sandet 6 4632 Bjaeverskov, Denmark
Contact: Phone Number: Email:	Mie Dyrholm +45 56 86 84 92 Mie.Dyrholm@CookMedical.com

Device Information

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

Predicate Device

The subject Lunderquist® Extra Stiff Wire Guide is substantially equivalent to the predicate Lunderquist® Extra Stiff Wire Guide (K220137, cleared 17 Feb 2022).

Device Description

The Lunderquist® Extra Stiff Wire Guides are 0.035 inch PTFE coated stainless steel wire guides consisting of a mandril and a 15 cm or 18 cm long coil. The mandril has a tapered end with a length of 11 cm and an additional 4 or 7 cm flexible tip. The Lunderquist wire guides are available in the following configurations:

Straight Lunderquist wire guides (TSMG-/-LES) are available in lengths of 90, 145, 180, 260, and 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.

Curved Lunderquist wire guides (TSCMG-/-LES) are available in lengths of 90, 145, 180, 260, and 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. The J-curve radius for the curved wire guides is either 3 mm or 7 mm.

Double Curved Lunderquist wire guides (TSCMG-/-LESDC) are available in lengths of 260 and 300 cm with a 4 cm flexible tip that includes an inner gold coil. The Double Curved Lunderquist wire guides have a large curve/J-curve radius of 75/15 mm.

Extended Double Curved Lunderquist wire guides (TSCMG-/-E-LESDC) are available in lengths of 260 and 300 cm with a 4 cm flexible tip that includes an inner gold coil. The Extended Double Curved Lunderquist wire guides have an extended large curve/J-curve radius of 55/15 mm.

Indications for Use

The Lunderquist Extra Stiff Wire Guides are intended to facilitate catheterization and/or placement of devices during vascular interventional procedures.

The Lunderquist Extra Stiff Wire Guides are intended for use in the aorta, including its access vessels and major adjacent vessels.

The Lunderquist Extra Stiff Wire Guides are auxiliary devices and hence not primary interventional devices themselves. Instead, they are intended to facilitate vascular access and/or delivery of over-the-wire medical devices during endovascular procedures, including TEVAR/EVAR procedures.

The Lunderquist Extra Stiff Wire Guides are both long and stiff; features that make them suitable for facilitating endovascular procedures that involve placement of large devices e.g., stent grafts in the aorta. The wire guides are not intended for coronary or neurovascular use.

Comparison to Predicate Device:

The subject device is substantially equivalent to the predicate Lunderquist Extra Stiff Wire Guide cleared under K220137. The principles of operation, design, materials of construction, manufacturing processes, packaging, sterilization process, and basic technological characteristics of the subject device are identical to the predicate device. The device labeling has been updated in alignment with the risk documentation, post market data and global harmonization of the labeling. The labeling updates the indications for use statement, specifically removing the vena cava and specifying the major vessels in alignment with postmarket data.

Technological Characteristics

The technological characteristics remain the same as for the predicate device.

The Lunderquist® Extra Stiff Wire Guides are 0.035 inch PTFE coated stainless steel wire guides consisting of a mandril and a 15 or 18 cm long coil. The mandril has a tapered end with a length of 11 cm and an additional 4 or 7 cm flexible tip. The device is supplied as single use in a Tyvek® peel pouch, sterilized by ethylene oxide gas.

Performance Testing

No changes to the design, manufacturing, sterilization, or principles of operation have been introduced with the subject device. Therefore, no performance testing was warranted in support of this Special 510(k).

Conclusion

The subject device is substantially equivalent to the predicate The Lunderquist Extra Stiff Wire Guide cleared under K220137. The design and technological characteristics of the subject device are identical to the predicate device. The changes proposed in this submission are to device labeling in alignment with risk documentation and in an effort to gain global harmonization of the labeling.