K042611

NOV 12 2004

COOK®

Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489
Phone: 800 468-1379
www.cookgroup.com

510(k) Summary

Submitted By:

WILLIAM COOK EUROPE APS
Sandet 6, dk-4632
Bjaeverskov, DENMARK

Contact:
Earl E. Knight III, MPA
Regulatory Affairs
Phone: (812) 339-2235
Fax: (812) 322-0281

Date Prepared:
September 23, 2004

Device:

Trade Name:	Lunderquist Extra Stiff Double Curved Exchange Wire Guide
Proposed Classification:	870.1330 DQX Class II, Cardiovascular

Predicate Devices:

The Lunderquist Extra Stiff Double Curved Exchange Wire Guide is similar in terms of intended use, materials of construction and technological characteristics to predicate devices designed for diagnostic and interventional procedures.

Device Description:

The Lunderquist Extra Stiff Double Curved Exchange Wire Guide has an outer diameter of .035 inches and is 260 cm long. The Lunderquist is a TFE-coated stainless steel wire guide with a double curved tip design, and a tapered, soft proximal end to ease device introduction. The double curved distal tip has 4 cm of tip flexibility.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by William Cook Europe. This device will undergo sterilization similar to the devices currently marketed and distributed. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

Test Data:

The Lunderquist Extra Stiff Double Curved Exchange Wire Guide was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. 4-Point Bend Testing
2. Flexing/Straightening Force
3. Tensile Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a guide wire.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Cook Incorporated
c/o Mr. Earl E. Knight III, MPA
Regulatory Affairs Specialist
P.O. Box 489
Bloomington, IN 47402-0489

Re: K042611
Trade/Device Name: Lunderquist Extra Stiff Double Curved Exchange Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 22, 2004
Received: October 25, 2004

Dear Mr. Knight:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K042611**

Device Name: Lunderquist Extra Stiff Double Curved Exchange Wire Guide

Indications For Use:

The Lunderquist Extra Stiff Double Curved Exchange Wire Guide is intended for complex diagnostic and interventional procedures where increased body, flexibility, and low surface friction of the wire guide are needed.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedrine

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K042611