DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 11, 2017

Cook Incorporated
Thomas Kardos
Vice President, Regulatory Affairs
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47402

Re: K163353
Trade/Device Name: Needle's Eye Snare Retrieval Set - 54cm
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: June 13, 2017
Received: June 14, 2017

Dear Thomas Kardos:

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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163353

Device Name
Needle's Eye Snare® Retrieval Set - 54 cm

Indications for Use *(Describe)*
The Needle's Eye Snare® Retrieval Set – 54cm is intended for use in patients requiring the percutaneous retrieval of indwelling catheters, cardiac leads, fragments of catheter tubing or wire guides and other foreign objects.

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

510(k) Number: K163353

Submitted By:

Thomas J. Kardos
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (724) 845-8621 x2225
Fax: (724) 845-2848
Date Prepared: July 7, 2017

Device:

Trade Name:	Needle's Eye Snare® Retrieval Set - 54cm
Common Name:	Snare
Classification Name:	Embolectomy Catheter
	DXE (21 CFR 870.5150)
Class/Panel:	Class II, Cardiovascular

Indications for Use:

The Needle's Eye Snare® Retrieval Set – 54cm is intended for use in patients requiring the percutaneous retrieval of indwelling catheters, cardiac leads, fragments of catheter tubing or wire guides and other foreign objects.

Predicate Device:

The devices, subject of this submission, are substantially equivalent to the predicate devices, the Needle's Eye Snare®, cleared on December 27, 1996 under 510(k) number K961992.

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Comparison to Predicate Device:

It has been demonstrated that the Needle's Eye Snare® Retrieval Set - 54cm is comparable to the predicate device, the Needle's Eye Snare® (K961992) is identical in terms of intended use, principles of operation, and basic technological characteristics to the predicate devices, and also identical in materials of construction to the predicate device. The only differences between the predicate and subject device are the specified length of the proposed device, which is 54cm versus the cleared device length of 94cm, and the inclusion of a 12 Fr Curved Inner Sheath as an accessory.

Device Description:

The Needle's Eye Snare® Retrieval Set- 54cm is a grasping device that forms a basket-like snare around the in-dwelling catheter, cardiac lead, fragment of catheter tubing, wire guide or other foreign object. The distal end is delivered to the vicinity of the lead through a long, flexible 12Fr. (O.D.) PTFE sheath placed coaxially within a 16Fr. (O.D.) PTFE Check-Flo® Introducer Sheath having a Check-Flo® Valve with stopcock at its proximal end. The device is comprised at the distal end of a nitinol wire needle's eye retrieval mechanism consisting of a "needle's eye" loop and "threader" with stainless steel sleeves housed within a PTFE protective cover sheath. The snare is activated through the forward advancement of the threader by fully depressing the plunger. The item is captured between the threader and needle's eye. The inner sheath is advanced forward closing the snare and securely capturing the lead or other foreign object. The Needle's Eye Snare® Retrieval Set - 54cm has nominal usable length of 54cm.

Test Data:

The following testing was provided to support a determination of substantial equivalence to the predicate device:

- Particulate Testing – Testing was performed to show that particulates from the device are comparable to the predicate and meet the requirements of USP 778. The predetermined acceptance criteria were met.