October 18, 2017

Cook Incorporated
Steven Lawrie
Regulatory Affairs Manager
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47402

Re: K170298
Trade/Device Name: Liberator Beacon Tip Locking Stylet
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter Stylet
Regulatory Class: Class II
Product Code: DRB
Dated: September 13, 2017
Received: September 14, 2017

Dear Steven Lawrie:

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 (DICE) 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 (DICE) 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)*

Device Name
Liberator® Beacon® Tip Locking Stylet

Indications for Use *(Describe)*
The Liberator® Beacon® Tip Locking Stylet is intended for use in patients requiring the percutaneous removal of cardiac leads, indwelling catheters and foreign objects, with a central lumen.

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

Liberator® Beacon® Tip Locking Stylet
21 CFR §870.1380
Date Prepared: January 30, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Steven Lawrie
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104518
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Liberator® Beacon® Tip Locking Stylet
Common Name:	Locking Stylet
Classification Name:	Stylet, Catheter
Classification Regulation:	21 CFR §870.1380, Product Code DRB
Device Class/Classification Panel:	Class II, Cardiovascular

Predicate Device:

- Locking Stylet 2 (K970690)

Device Description:

The Liberator® Beacon® Tip Locking Stylet is a specialized stylet that can be inserted through a cardiac lead's inner conductor lumen, once the proximal connector has been removed. The stylet can then be locked into position within the lead's distal portion allowing for the delivery of tractional forces helpful during the extraction procedure.

The Liberator® Beacon® Tip Locking Stylet has a braided Nickel-Chromium integral extender (handle). The locking mechanism that is located at the distal end of the stylet is comprised of a uniquely shaped stainless steel wire-locking coil segment attached to a central stainless steel stylet wire. This locking stylet is activated through the forward advancement of a stainless steel cannula that surrounds the central stainless steel stylet wire. Upon activation by the cannula, the wire-locking coil segment at the distal end of

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the stylet is advanced forward and is compressed. This compression causes the stacking of successive helices of the wire-locking coil. This stacking results in the outward radial displacement of a number of the wire-locking coil's helices against and into the lead conductor coil through which it has been inserted. This outward radial displacement creates the locking engagement of the Liberator® Beacon® Tip Locking Stylet to the lead conductor central or inner lumen. The device is available in a single size compatible with the internal diameter dimensions of many leads and catheters with a central lumen. Stylet wires for checking lead patency are available separately; they consist of a molded plastic handle on a 0.038 cm (0.015 inches) stainless steel wire, with a wire length of 65 cm.

Intended Use:

The Liberator® Beacon® Tip Locking Stylet is intended for use in patients requiring the percutaneous removal of cardiac leads, indwelling catheters and foreign objects, with a central lumen.

Comparison to Predicate:

The subject device is substantially equivalent to the predicate in that it has the same intended use as the predicate. They also have similar technological characteristics, methods of operation, and materials of construction. The substantial equivalence comparison is provided below.

Substantial Equivalence Table

	PREDICATE DEVICE	**SUBJECT DEVICE**
	Locking Stylet 2 (K970690)	**Liberator® Beacon® Tip Locking Stylet (Subject of this Submission)**
Regulation	21 CFR §870.1330, Catheter Guide Wire	21 CFR §870.1380, Catheter Stylet
Product Code	DQX	DRB
Classification	II	II
Indications for Use	The Locking Stylet 2 is intended for use during the percutaneous removal of cardiac leads, indwelling catheters and foreign objects having a central lumen.	The Liberator® Beacon® Tip Locking Stylet is intended for use in patients requiring the percutaneous removal of cardiac leads, indwelling catheters and foreign objects, with a central lumen
Method of activation	Handle Slide Mechanism	Identical
Stylet Wire	304 Stainless Steel	Identical

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Cannula	304 Stainless Steel	Identical
Locking mechanism	Wire and Collar – 304 Stainless Steel	Wire Bundle – 304 Stainless Steel
Radiopaque Marker	N/A	Platinum clad Tantalum
Solder	Silver Bearing (6% Ag / 94% Sn)	Identical
Latch Clip	304 Stainless Steel	302 Stainless Steel
Cable	N/A	304 Stainless Steel
Wire (Handle)	Nickel-Chromium	Identical
Method of operation	The Locking Stylet 2 is inserted into the central lumen of a cardiac lead or catheter and advanced to the distal end. The latchpin, which is inserted into the pin hole on the tubular handle keeping the device in the disengaged position, is removed. To engage, the tubular handle portion of the Locking Stylet 2 is pushed forward while holding the loop handle stationary. This causes the wire exiting the proximal end of the distal cannula to protrude and engage into the inner surface of the central lumen. The captured indwelling object is then withdrawn with the Locking Stylet 2 by gently pulling on the loop handle while maintaining tension between the tubular handle portion and loop handle.	The Liberator® Beacon® Tip Locking Stylet is inserted into the central lumen of a cardiac lead or catheter and advanced to the distal end. The latchpin, which is inserted into the pin hole on the tubular handle keeping the device in the disengaged position, is removed. To engage, the tubular handle portion of the Liberator® Beacon® Tip Locking Stylet is pushed forward while holding the integral wire extender stationary. This causes the wire bundle exiting the proximal end of the distal cannula to protrude and engage into the inner surface of the central lumen. The captured indwelling object is then withdrawn with the Liberator® Beacon® Tip Locking Stylet by gently pulling on the loop handle while maintaining tension between the tubular handle portion and loop handle.
Activation mechanism	Advance cannula to lock stylet	Identical
Working Length (cm)	65 cm	70 cm
Overall Length (cm)	72 cm	140 cm
Locking Mechanism	Engagement wire	Wire bundle
Operating Range	.017 to .032 inches	.016 to .032 inches
Other components	None	Stylet wires (available separately)

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified design requirements:

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Liberator® Beacon® Tip Locking Stylet

- Complete Device Test – Testing demonstrated that the complete device withstood the established minimum pull strength force. The acceptance criterion was met.
- Collar Tubing Test – Testing demonstrated that the collar tubing materials and solder joints withstood the established minimum pull strength force. The acceptance criterion was met.
- Collar Cable Test – Testing demonstrated that the collar cable materials and solder joints withstood the established minimum pull strength force. The acceptance criterion was met.
- Mechanical Pull Test – Testing demonstrated that the device locked into a simulated cardiac lead withstood the established minimum pull strength force. The acceptance criterion was met.
- Radiopacity Test – Testing demonstrated that the distal end of the locking stylet is radiopaque. The acceptance criterion was met.
- Biocompatibility testing – Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, hemolysis, partial thromboplastin time, complement activation, and material mediated pyrogenicity were performed to ensure the biocompatibility of the subject device.

Stylet Wires

- Pull strength – Testing demonstrated that the stylet wire withstood the established minimum pull strength force. The acceptance criterion was met.
- Cardiac Lead Insertion / Retraction – Testing demonstrated that the stylet wires can pass in and out of a “wet” lead coil a total of two cycles. The acceptance criterion was met.
- Biocompatibility testing – Testing performed for the Liberator® Beacon® Tip Locking Stylet is also applicable to this component.

The results of these tests show that the subject device meets the design input requirements based on the intended use and support the determination that this device is substantially equivalent to the predicate device.