December 15, 2017

Cook Incorporated
Colin Jacob
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K173687
Trade/Device Name: Strange Bile Duct Stone Exploration Set
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: LQR, GCD, GBZ, OCY, GCB
Dated: November 30, 2017
Received: December 1, 2017

Dear Colin Jacob:

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. However, you are responsible to determine that the medical devices you use as components in the Strange Bile Duct Stone Exploration Set have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K173687

Device Name
Strange Bile Duct Stone Exploration Set

Indications for Use *(Describe)*
The Strange Bile Duct Stone Exploration Set is intended to be used for cholangiography and bile duct stone retrieval using fluoroscopy. The device is indicated for adults only.

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.

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COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) Summary

Strange Bile Duct Stone Exploration Set
(21 CFR §807.92)
Date Prepared: November 30, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Colin Jacob
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47402
Contact Phone Number:	(812) 335-3575 x 104965
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Strange Bile Duct Stone Exploration Set
Panel:	Gastroenterology/Urology
Regulation:	21 CFR § 876.5010
Regulation Name:	Biliary catheter and accessories
Primary Product Code:	LQR
Secondary Product Codes:	GCD, GBZ, OCY, GCB

Predicate Devices:
The predicate device is the NCompass Nitinol Stone Extractor (K173009).

Device Description:
The Strange Bile Duct Stone Exploration Set is provided sterile for single-use only. The set consists of:

- a 115 centimeter long NCompass Nitinol Tipped Stone Extractor with Tuohy Borst adapter
- a 7.5 French, double lumen, 40 centimeter long radiopaque polyurethane cholangiography catheter with a preloaded inner catheter;
- a 10 French, 12 centimeter long introducer catheter with preloaded needle stylet; and
- a 125 centimeter long, polytetrafluoroethylene coated wire guide.

Indications for Use:
The Strange Bile Duct Stone Exploration Set is intended to be used for cholangiography and bile duct stone retrieval using fluoroscopy. The device is indicated for adults only.

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Comparison to Predicates:

The Strange Bile Duct Exploration Set and the predicate device, the NCompass Nitinol Stone Extractor (K173009), are substantially equivalent in that these devices have the same intended use and principles of operation, and similar indications for use. The differences between the subject device and the predicate device include:

- Additional components.
- Assist in cholangiography via the additional components.

A comparison table on the following page elaborates on the features of the subject device and the predicate device.

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Substantial Equivalence Comparison

		PREDICATE DEVICE	SUBJECT DEVICE
		NCompass Nitinol Stone Extractor (K173009)	**Strange Bile Duct Stone Exploration Set**
Regulation Number		21 CFR § 876.5010	IDENTICAL TO PREDICATE
Primary Product Code		LQR	IDENTICAL TO PREDICATE
Classification		II	IDENTICAL TO PREDICATE
Indications for Use		For extraction of stones or debris during biliary surgical procedures	For cholangiography and bile duct stone retrieval using fluoroscopy
One-time Use		Yes	IDENTICAL TO PREDICATE
Duration of Use		Limited (≤ 24 hours)	IDENTICAL TO PREDICATE
Principles of Operation		Basket deployment from sheath into the biliary duct location	Basket deployment from sheath into the biliary duct location. In addition to cholangiography of the duct.
Imaging Technique to Visualize Device		Fluoroscopy	IDENTICAL TO PREDICATE
Basket	**Tip Material**	Stainless steel	IDENTICAL TO PREDICATE
	Wire Material	Nitinol	IDENTICAL TO PREDICATE
	Wire Configuration	12-wire bulb configuration	IDENTICAL TO PREDICATE
	Length (cm)	1.9-2.3	IDENTICAL TO PREDICATE
	Outer Diameter when Deployed (cm)	1.5	IDENTICAL TO PREDICATE
Catheter	**Material**	Braided stainless steel tubing coated with polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), and polyimide	IDENTICAL TO PREDICATE
	Length (cm)	115	IDENTICAL TO PREDICATE
	Outer Diameter (Fr)	2.4	IDENTICAL TO PREDICATE
Adapter		Tuohy Borst adapter	IDENTICAL TO PREDICATE
Additional Components		None	Cholangiography catheter, wire guide, introducer catheter with preloaded needle stylet
Packaging		Polyethylene-Polyester/Tyvek	IDENTICAL TO PREDICATE
Sterilization Method		Ethylene Oxide	IDENTICAL TO PREDICATE
Sterility Assurance Level (SAL)		10^{-6}	IDENTICAL TO PREDICATE

Technological Characteristics:

The subject device, Strange Bile Duct Stone Exploration Set, was subjected to applicable non-clinical testing to assure reliable design and performance under the testing parameters. Testing includes:

- Dimensional and Compatibility Evaluation of subject device set (Accelerated Aged)

All pre-determined acceptance criteria were met.

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Conclusion:

The Strange Bile Duct Stone Exploration Set meets the design input requirements based on the intended use. Furthermore, the results and comparison supports the conclusion that the Strange Bile Duct Stone Exploration Set does not raise new questions of safety or effectiveness and support a determination of substantial equivalence.