December 12, 2017

Cook Incorporated
Erum B. Nasir
Regulatory Affairs Team Lead
750 Daniels Way, P.O. Box 489
Bloomington, IN 47404

Re: K170898
Trade/Device Name: Wittich Nitinol Stone Basket
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: LQR, FFL
Dated: November 8, 2017
Received: November 9, 2017

Dear Erum B. Nasir:

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.

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)*

K170898

Device Name
Wittich Nitinol Stone Basket

Indications for Use *(Describe)*

The Wittich Nitinol Stone Basket is intended for placement through a percutaneous tract for removal of stones (calculi) or stone fragments from anatomic structures such as the gallbladder, biliary tract, renal pelvis, and ureter.

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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Section 1.0 510(k) Summary

Wittich Nitinol Stone Basket
21 CFR, §876.5010
Date Prepared: December 10, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Erum B. Nasir, MS
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102607
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Wittich Nitinol Stone Basket
Common Name:	Dislodger, Stone, Biliary Dislodger, Stone, Basket, Ureteral, Metal
Classification Name:	Biliary Catheter and Accessories Ureteral Stone Dislodger
Regulation:	21 CFR, §876.5010 21 CFR, §876.4680 (510(k) exempt)
Product Code:	LQR FFL (510(k) exempt)
Device Class:	II
Classification Panel:	Gastroenterology/Urology

Predicate Devices:

The Wittich Nitinol Stone Basket is substantially equivalent to the predicate device, the Wittich Nitinol Stone Basket (K902944) cleared for market by FDA on September 12, 1990.

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Device Description:

The Wittich Nitinol Stone Basket is comprised of a basket catheter with a loading sleeve, an introducer sheath, and a dilator. The basket is designed with a six-wire bulb configuration and is manufactured from nitinol wire. The nitinol wires are soldered together to a stylet wire which is secured inside the basket catheter shaft. The loading sleeve is used to support the insertion of the basket catheter into the introducer sheath.

The introducer sheath is manufactured from radiopaque fluorinated ethylene propylene and is designed with a radiopaque tip near the distal end of the introducer for tip visibility. Additionally, the distal end of the introducer sheath is angled to facilitate directional control. The matched dilator is manufactured from polyethylene tubing and is tapered for a smooth transitional fit within the matched introducer sheath.

Intended Use:

The Wittich Nitinol Stone Basket is intended for placement through a percutaneous tract for removal of stones (calculi) or stone fragments from anatomic structures such as the gallbladder, biliary tract, renal pelvis, and ureter.

Comparison to Predicates:

The Wittich Nitinol Stone Basket and the predicate device, Wittich Nitinol Stone Basket (K902944), are substantially equivalent in that these devices are identical in principles of operation and fundamental technologies. The differences between the subject device and the predicate device, including materials, dimensions, and minor modification to the indications for use, do not raise any new issues of safety or effectiveness. The substantial equivalence of the modified subject device is supported by testing.

Table 2.0-1 Substantial Equivalence Comparison

		Wittich Nitinol Stone Basket (K902944)	Wittich Nitinol Stone Basket (Subject of this submission)
Regulation Number		21 CFR §876.5010	21 CFR §876.5010 & 21 CFR §876.4680
Product Code		LQR	LQR & FFL
Classification		Class II	Identical
Intended Use/Indications for Use		Used for nonoperative removal of stones from the biliary tract, renal pelvis and ureter	Intended for placement through a percutaneous tract for removal of stones (calculi) or stone fragments from anatomic structures such as the gallbladder, biliary tract, renal pelvis and ureter
Basket	**Shaft**	Polyethylene	Identical
	Basket Wire	Nitinol wire	Identical
	Shrink Tube	Gray Slate, Semi-Rigid	Identical
	Loading Sleeve	Tetrafluoroethylene	Identical
	Solder	Allstate	Identical
		Silweld Solder	Identical
	Sphere	Tevdek Suture	Silicone Elastomer
	Notched Cannula	Stainless Steel	Identical
	Stylet Wire	Stainless Steel	Identical
	Inner Coil	Stainless Steel	Identical
	Outer Diameter (cm)	2.0	1.8 and 2.2
	Length (cm)	4.5	2.5 and 4.5
Introducer Sheath	**Shaft**	Radiopaque Fluorinated Ethylene Propylene	Identical
	Connector Cap	Polyamide Nylon 6	Identical
	Adapter	Polyamide Nylon 6	Identical
	Adhesive	Loctite	Identical
	Distal End	Tungsten/Rhenium Band	Fluorinated Ethylene Propylene Tungsten
	Outer Diameter (Fr)	12	8.5 and 12.0
	Length (cm)	24	24 and 50
Dilator	**Shaft**	Polyethylene	Identical
	Adapter	High Density Polyethylene	Identical
	Cap	Acetal	Identical
Packaging		Polyethylene-Polyester/Tyvek	Identical
Sterilization		Ethylene oxide	Identical
Sterility Assurance Level (SAL)		10^{-6}	Identical

Test Data:

The following tests have been performed to demonstrate that the application device met applicable design and performance requirements:

- Dimensional and Compatibility - (Basket Catheter, Introducer, and Dilator) - Testing showed that dimensions and component compatibility was adequate for clinical use.
- Multiple Stone Retrieval Testing - Testing performed per FDA 510(k) Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology showed the Basket Catheter with Loading Sleeve and the Introducer Sheath was able to track, deploy, and retrieve a simulated stone (approximately eight (8) mm in diameter) ten times through a tube bent at approximately ninety degrees, without damage to the test article.
- Basket Catheter Shaft, Basket-to Basket Shaft Solder Joint, and Hub-To-Shaft Joint Tensile – Testing in accordance with JIS T 3244:2011 showed the peak load of catheter shaft section was greater than or equal to 10 N.
- Basket Catheter Single Loop and Silicone Sphere to Basket Wire Joint Tensile Testing – Testing in accordance with JIS T 3244:2011 showed the peak load of a single loop of the basket catheter and silicone sphere to basket wire joint was greater than or equal to 10 N.
- Introducer Sheath Shaft, Introducer Sheath Hub-to-Shaft – Testing in accordance with BS EN ISO 11070: 2014 showed the peak load of the introducer sheath shaft and introducer sheath hub-to-shaft bond were greater than or equal to 15 N.
- Introducer Distal Tip Bond Tensile – Testing in accordance with BS EN ISO 11070 showed the peak load of shaft-to-tip was greater than or equal to 15 N.
- Radiopacity – Testing following the method described in ASTM F6540-12, "Standard Test Methods for Determining Radiopacity for Medical Use" showed the radiopacity of the Wittich Nitinol Stone Basket introducer sheath was determined to be non-inferior to the radiopacity of the selected comparative device.
- Introducer Sheath Kink Radius – Testing showed the kink radius was less than or equal to 30 mm.
- Dilator Shaft/Hub-to-Shaft Tensile – Testing in accordance with BS EN ISO 11070 showed the peak load of the dilator shaft and the hub-to-shaft were greater than or equal to 10N and 15 N, respectively.

- Biocompatibility testing – Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, and acute systemic toxicity demonstrated the biocompatibility of the subject devices.

For these tests, all pre-determined acceptance criteria were met. The results of these tests showed that the subject devices met the design input requirements based on the intended use, and support the conclusion that these devices do not raise new questions of safety or effectiveness and support a determination of substantially equivalence to the predicate device.