June 22, 2018

Cook Incorporated
Hui (Alice) Ouyang
Regulatory Scientist
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

Re: K173414
Trade/Device Name: Advance Biliary Balloon Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: GCA
Dated: May 23, 2018
Received: May 25, 2018

Dear Hui (Alice) Ouyang:

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 kit 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 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,

Jeffrey W. Cooper -S
2018.06.22 14:35:44
-04'00'

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173414

Device Name
Advance Biliary Balloon Catheter

Indications for Use *(Describe)*
The Advance Biliary Balloon Catheter is indicated for laparoscopic and general surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.

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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Advance Biliary Balloon Catheter

21 CFR §807.92

Date Prepared: June 21, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Colin Jacob Hui Ouyang, PhD, RAC
Applicant Address:	Cook Incorporated P.O. Box 489 750 Daniels Way Bloomington, IN 47402
Contact Phone Number:	(812) 335-3575 x 105421
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Advance Biliary Balloon Catheter
Device Common Name:	Biliary catheter for stone removal that may also allow for irrigation and contrast injection
Classification Name:	Biliary catheter and accessories
Classification Regulation:	21 CFR §876.5010, GCA
Device Classification:	Class II
Review Panel:	Gastroenterology/Urology
Office of Device Evaluation:	Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD) Gastroenterology Devices Branch (GEDB)

Predicate Devices:

The predicate device is the Taut Biliary Balloon Catheter (K011018) from Taut, Inc.

Reference Devices:

To support the use of an 8-mm balloon catheter in the biliary tree:

- Olympus Single Use Balloon Dilator MaxPass (cleared via K050502)
- Boston Scientific's Hurricane RX Biliary Balloon Dilatation Catheter (cleared via K130484)

For biocompatibility of the subject device:

- ATB All-Terrain Balloon PTA Dilatation Catheter (cleared via K033875)
- Advance 35LP Low Profile PTA Balloon Dilation Catheter (cleared via K091527)

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Device Description:

The Advance Biliary Balloon Catheter is a sterile, one-time use, device. The device is a double-lumen catheter manufactured with a nylon shaft. The distal tip of the catheter consists of a nylon balloon and is available in diameters of 6 and 8 millimeters, and a length of 4.0 centimeters. The Advance Biliary Balloon Catheter accepts a 0.035-inch diameter wire guide. Table 1 lists the dimensions of balloon catheter models of this submission.

Table 1: Dimensions of balloon catheter models of this submission

Balloon Catheter Model	Balloon		Catheter Shaft	
	Inflated Diameter	Length	Outer Diameter	Working Length
ATB 8-mm	8 mm	4 cm	5 Fr	40 cm
PTA 8-mm	8 mm	4 cm	5 Fr	80 cm
PTA 6-mm	6 mm	4 cm	5 Fr	80 cm

Indications for Use:

The Advance Biliary Balloon Catheter is indicated for laparoscopic and general surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.

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Comparison to Predicate:

		PREDICATE DEVICE	SUBJECT DEVICE
		Taut Balloon Catheter, Model 50640 (K011018)	**Advance Biliary Balloon Catheter**
Regulation Number		21 CFR §876.5010	IDENTICAL TO PREDICATE
Product Code		GCA	IDENTICAL TO PREDICATE
Classification		II	IDENTICAL TO PREDICATE
Indications for Use		The Taut Biliary Balloon Catheter Indicated for use in laparoscopic and general surgical procedures for the dilation of vessels to facilitate common bile duct exploration. The Taut Biliary Balloon Catheter may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.	The Biliary Balloon Catheter is indicated for laparoscopic and general surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.
One-time Use		Yes	IDENTICAL TO PREDICATE
Duration of Use		Limited (≤ 24 hours)	IDENTICAL TO PREDICATE
Imaging Technique to Visualize Device		Fluoroscopy, Laparoscopic Imaging	IDENTICAL TO PREDICATE
Principles of Operation		Balloon inflation to open or widen biliary lumen	IDENTICAL TO PREDICATE
Delivery System		Over-the-wire	IDENTICAL TO PREDICATE
Balloon of Catheter	**Inflated Outer Diameter (mm)**	6	6, 8
	Length (cm)	4.0	IDENTICAL TO PREDICATE
	Material	Nylon	Nylon
Shaft of Catheter	**Outer Diameter (Fr)**	5	IDENTICAL TO PREDICATE
	Length (cm)	75	40, 80
	Material	Unknown	Nylon copolymer
	Marker Bands	Yes	IDENTICAL TO PREDICATE
	Number of Lumens	2	IDENTICAL TO PREDICATE
	Wire Guide Compatibility (in)	0.035	IDENTICAL TO PREDICATE
Sterilization Method		Ethylene Oxide	IDENTICAL TO PREDICATE

Both the predicate and subject device have the same intended use, similar indication, and similar technological characteristics. The differences in indication for use and technological characteristics do not raise different questions of safety or effectiveness because:

- **Indication for use:** both devices are indicated for laparoscopic and general surgical procedures for the dilation of vessels (subject device specifies the “cystic duct”) to

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facilitate common bile duct exploration. Vessels are usually associated with the vascular system; therefore, the more appropriate term for the location in which the subject device is used is cystic duct. This provides the user a clearer understanding of the intended use of the subject device compared to the predicate device. Both, subject device and predicate device are indicated to be used in the same anatomical location with the same indication. The predicate device is also indicated for injection of contrast medium for fluoroscopic visualization of the bile ducts, while the subject device is not indicated for such application.

- **Inflated Balloon Outer Diameter**: The balloon diameter of the predicate is 6 mm. The balloon diameter of the subject device is 6 or 8 mm. The additional 8-mm diameter of balloon catheter is provided to accommodate various sizes of the cystic duct. During the common bile duct exploration procedure, the biliary ductal anatomy is first identified under fluoroscopy or laparoscopic ultrasound. The anatomy information allows physicians to choose the appropriate balloon size for dilation, if the cystic duct needs to be dilated for further evaluation / procedure. An 8 mm diameter balloon is commonly used to dilate the cystic duct during common bile duct exploration, and is referenced in multiple publications regarding management of choledocholithiasis. Other legally marketed reference devices indicated to dilate the biliary tree are the Olympus Single Use Balloon Dilator MaxPass (K050502, has balloon diameters of 4, 6, and 8 mm) and Boston Scientific's Hurricane RX Biliary Balloon Dilatation Catheter (K130484, has balloon diameters of 4, 6, and 8 mm). The 8-mm balloon diameter from the subject device does not raise different questions of safety or effectiveness comparing to the predicate
- **Material of Balloon and Catheter Shaft**: The subject device has a nylon balloon and a nylon-copolymer shaft. The predicate has a nylon balloon (exact chemical formula is known) and a shaft with unknown material. Nylon is commonly used in medical devices for various applications and is considered biologically safe. The subject device, including the same nylon balloon material and nylon copolymer shaft material, has been previously cleared for dilation of peripheral vessels via K033875 and K091527. Biocompatibility and performance testing on the subject device, including the balloon material and catheter shaft has demonstrated that the balloon material and catheter shaft is safe for its intended use and duration.
- **Catheter Working Length**: The catheter component of the predicate device is available in a length of 75 cm while the subject device is available in lengths of 40 cm and 80 cm.

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These two catheter lengths provided by the subject device accommodate various lengths of biliary tracts and patient anatomy. The distal end of the catheter contains marker bands to confirm the location of the catheter during the procedure. Therefore, the additional catheter length of the subject device does not raise different questions of safety or effectiveness when compared to the predicate device.

Technological Characteristics:

The subject device, Advance Biliary Balloon Catheter, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below:

- Biocompatibility – Data from the reference devices, the ATB All-Terrain Balloon PTA Dilatation Catheter (cleared via K033875) and the Advance 35LP Low Profile PTA Balloon Dilation Catheter (cleared via K091527), were leveraged to mitigate biocompatibility of the subject device.
- Balloon Burst Pressure – Balloon burst pressure was performed to evaluate the balloon failure pressure of the subject device. Test results indicated an acceptable balloon burst pressure.
- Balloon Compliance – Balloon compliance was performed to evaluate the balloon compliance of the subject device. Test results indicated acceptable balloon compliance.
- Tensile of Distal Bond of Balloon to Catheter Shaft – Tensile testing was performed to ensure the appropriate bond strength of the distal bond of balloon to catheter shaft. Test results indicated that the bond strength is appropriate.
- Fatigue Test – Fatigue testing was performed to ensure balloon stability. Test results indicate that the balloon fatigue is appropriate.
- Tensile Test of Hub-to-Shaft Bond – Tensile testing was performed to ensure the appropriate bond strength of the hub to catheter shaft. Test results indicated that the bond strength is appropriate.
- Tensile Test of the Proximal Bond of the Balloon to Catheter Shaft – Tensile testing was performed to ensure the appropriate bond strength of the proximal bond of balloon to catheter shaft. Test results indicated that the bond strength is appropriate.
- Tensile Test of the Tip-to-Shaft Bond – Tensile testing was performed to ensure the appropriate bond strength of the tip to catheter shaft. Test results indicated that the bond strength is appropriate.

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- Tensile Test of the Soft Tip Bond – Tensile testing was performed to ensure the appropriate bond strength of the soft tip to catheter shaft. Test results indicated that the bond strength is appropriate.

Conclusion:

The results of biocompatibility and performance testing confirm that the Biliary Balloon Catheter meets the design input requirements based on the intended use. Furthermore, these results support a determination that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device, Taut Biliary Balloon Catheter (K011018).