June 26, 2019

Cook Incorporated
Rohini Patel, Ph.D.
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K182832
Trade/Device Name: Cope Pediatric Gastrointestinal Suture Anchor Set, Enterostomy Suture Anchor Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KGC
Dated: May 28, 2019
Received: May 30, 2019

Dear Rohini Patel:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the Cope Pediatric Gastrointestinal Suture Anchor Set and the Enterostomy Suture Anchor 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Shani P. Haugen, Ph.D.
Acting Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K182832

Device Name
Cope Pediatric Gastrointestinal Suture Anchor Set
Enterostomy Suture Anchor Set

Indications for Use *(Describe)*
The Cope Pediatric Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to the introduction of interventional catheters and can stay in place for up to 14 days in infant, child, and adolescent populations.

The Enterostomy Suture Anchor Set is intended for anchoring the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters and stay in place for up to 14 days in child, adolescent, and adult populations.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) Summary

K182832
Cope Pediatric Gastrointestinal Suture Anchor Set
Enterostomy Suture Anchor Set
21 CFR §876.5010
Date Prepared: 24 June 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Rohini Patel
Email:	RegSubmission@CookMedical.com
Contact Phone Number:	(812) 335-3575 x104516
Contact Fax number:	(812) 332-0281

Device Information:

Trade Name:	**Cope Pediatric Gastrointestinal Suture Anchor Set** **Enterostomy Suture Anchor Set**
Regulation Name:	Gastrointestinal tube and accessories
Classification Regulation:	21 CFR §876.5980, Product Code KGC
Device Class:	Class II
Classification Panel:	Gastroenterology/Urology

Predicate Device:

The predicate device for the Cope Pediatric Gastrointestinal Suture Anchor Set and Enterostomy Suture Anchor Set is the Modified Cope Suture Anchor (K873606, Cook Incorporated) cleared on June 17, 1988.

Device Description:

This bundled submission includes two devices: Cope Pediatric Gastrointestinal Suture Anchor Set and Enterostomy Suture Anchor Set. Both subject devices include two suture anchors that are identical.

The Cope Pediatric Gastrointestinal Suture Anchor Set is available in two set configurations. Both set configurations are supplied with two suture anchors that are identical. The first suture anchor is pre-loaded in the lancet-tip introducer needle. The

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

second suture anchor may come pre-loaded in the blunt-tip backload needle. A wire guide is supplied if the second suture anchor comes pre-loaded in the backload needle. The suture anchor is made of a 0.025-inch stainless steel anchor and a 30-cm suture. The anchor is either 2 cm or 1.3 cm long. The suture is the 5-0 size Tevdek® and one end of the suture is bonded at the center of the anchor. The introducer needle is made of 19-gauge stainless steel cannula in the length of 7 cm. The distal tip of the introducer needle is lancet bevel. Similarly, the backload needle is made of 19-gauge stainless steel cannula and 3 cm long. The distal tip of the backload needle is blunt. The wire guide is made of 0.025-inch stainless steel coil and 80 cm in length. Again, the wire guide is only supplied in the set configuration that the suture anchor is pre-loaded in the introducer needle.

The Enterostomy Suture Anchor Set is supplied with two suture anchors, the lancet-tip introducer needle, the blunt-tip backload needle, the wire guide, and the dilator. The suture anchors are pre-loaded in the backload needle. The suture anchor is made of a 0.025-inch stainless steel anchor and a 30-cm suture. The suture is the 5-0 size Tevdek® and one end of the suture is bonded at the center of the anchor. The introducer needle is made of 18-gauge stainless steel cannula in the length of 7 cm. The distal tip of the introducer needle is lancet bevel. Similarly, the backload needle is made of 18-gauge stainless steel cannula and 5 cm long. The distal tip of the backload needle is blunt. The wire guide is made of 0.035-inch stainless steel coil and 80 cm in length. The wire guide is coated in polytetrafluoroethylene. The dilator is made of 8 French polyethylene tubing and 20 cm in length. The distal end of the dilator is tapered to 0.035 inches in diameter.

Where Chait Enterostomy Suture Anchor Set is mentioned instead of Enterostomy Suture Anchor Set in the submission, the references are made to the identical product. The “Chait” naming convention is used in the internal purposes.

Indications for Use:

The Cope Pediatric Gastrointestinal Suture Anchor Set and Enterostomy Suture Anchor Set are used for anchoring the anterior wall of the hollow viscus to the abdominal walls for up to 14 days. The exact verbiage of the intended use can be found in Table 1.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Table 1 Subject Device Intended Use

	Intended Use
Cope Pediatric Gastrointestinal Suture Anchor Set	Intended for anchoring the anterior wall of the stomach to the abdominal wall prior to the introduction of interventional catheters and can stay in place for up to 14 days in infant, child, and adolescent populations
Enterostomy Suture Anchor Set	Intended for anchoring the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters and stay in place for up to 14 days in child, adolescent, and adult populations

Comparison to Predicate Device:

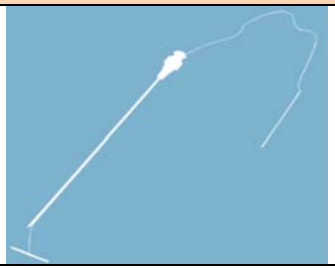
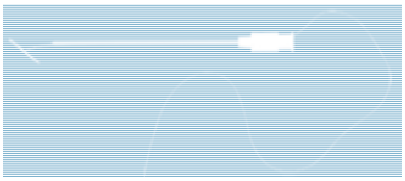
The subject devices, Cope Pediatric Gastrointestinal Suture Anchor Set and Enterostomy Suture Anchor Set, and the predicate device, the Modified Cope Suture Anchor (K873606), are substantially equivalent in that these devices have similar intended use and technological characteristics and are identical in method of placement.

The anchor material, introducer needle cannula material, wire guide material, number of sutures per anchor, and mode of operation are identical between the subject device Cope Pediatric Gastrointestinal Suture Anchor Set and the predicate device Modified Cope Suture Anchor (K873606). The differences between the subject device and predicate device, including target patient population, suture materials and dimensions, anchor dimensions, number of anchors, inclusion of a backload needle, suture securement method, and indications for use verbiage, do not raise any new questions of safety and/or effectiveness. The substantial equivalence comparison of the subject device, Cope Pediatric Gastrointestinal Suture Anchor Set, and the predicate device, Modified Cope Suture Anchor Set, is provided in Table 2 below.

Table 2 Substantial Equivalence Comparison Table – Cope Pediatric Gastrointestinal Suture Anchor Set

	Modified Cope Suture Anchor K873606	Cope Pediatric Gastrointestinal Suture Anchor Set Subject Device	
		Pre-Loaded	Un-Loaded
Regulation Number	876.5010	876.5980	
Product Code	FGE	KGC	
Classification	II	II	
Intended Use	Used for retaining hollow viscera prior to introduction of interventional catheters	Intended for anchoring the anterior wall of the stomach to the abdominal wall prior to the introduction of interventional catheters and can stay in place for up to 14 days in infant, child, and adolescent populations	

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

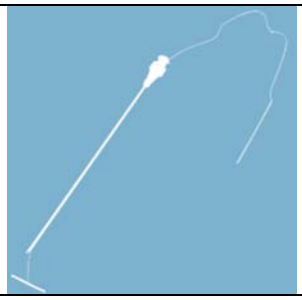
		Modified Cope Suture Anchor K873606		Cope Pediatric Gastrointestinal Suture Anchor Set Subject Device			
				Pre-Loaded		Un-Loaded	
Device Picture							
Anchor	**Material**	Stainless Steel (T-302 or T-304)		Stainless Steel (T-304)			
	Dimensions	**Diameter**	**Length**	**Diameter**	**Length**	**Diameter**	**Length**
		0.038 in	2 cm	0.025 in	2 cm	0.025 in	1.3 cm
	Count	1		2 (second anchor loaded in backload needle)		2 (1 anchor loaded, 1 anchor un-loaded)	
Suture	**Material**	Polydek® suture		Tevdek® suture			
	USP Size	4-0		5-0			
	Length	40 cm		30 cm			
	Count	1		Identical (1 per anchor)			
	Proximal suture needle	Yes		No			
Introducer needle	**Material, needle**	Stainless Steel		Identical			
	Material, hub	Polycarbonate		Polypropylene			
	Distal tip	Lancet		Identical			
	Dimensions	**Diameter**	**Length**	**Diameter**	**Length**	**Diameter**	**Length**
		18 G	12 cm	19 G	7 cm	19 G	7 cm
Backload needle	**Material**	Not included		Stainless Steel		Identical (the second anchor is provided without backload needle)	
	Distal tip			Blunt			
	Dimensions			**Diameter**	**Length**		
				19 G	3 cm		
Wire guide	**Material**	Stainless Steel (T-302 or T-304)		Stainless Steel (T-304)		Not included	
	Distal tip	Flexible		Flexible			
	Coating	Not coated		Not coated			
	Dimensions	**Diameter**	**Length**	**Diameter**	**Length**		
		0.038 in	80 cm	0.025 in	80 cm		
Indwell period		10-14 days		Up to 14 days			
Suture securement method		Secured to skin		Wrap the ends of the suture around gauze rolls and secure in place			
Mode of operation		Loaded anchor is deployed into the stomach as the wire guide pushes it from the proximal end of the introducer needle. After the tract formation, the anchor is removed by cutting the suture and allow their passage via the gastrointestinal system.		Identical			
One-time Use		Yes		Identical			

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

	Modified Cope Suture Anchor K873606	Cope Pediatric Gastrointestinal Suture Anchor Set Subject Device	
		Pre-Loaded	Un-Loaded
Sterilization, SAL	ETO, 10^{-6}	Identical	
Packaging	Tyvek peel-open pouch	Identical	

The anchor material, introducer needle material, wire guide material, number of sutures per anchor, and mode of operation are identical between the subject device Enterostomy Suture Anchor Set and the predicate device Modified Cope Suture Anchor (K873606). The differences between the subject device and the predicate device, including target patient population, suture materials and dimensions, anchor dimensions, number of anchors, introducer needle dimensions, inclusion of a backload needle, wire guide dimensions and coating, inclusion of a dilator, suture securement method, and indications for use verbiage do not raise any new questions of safety and/or effectiveness. The substantial equivalence comparison of the subject device, Enterostomy Suture Anchor Set, and the predicate device, Modified Cope Suture Anchor Set, is provided in Table 3 below.

Table 3 Substantial Equivalence Comparison – Enterostomy Suture Anchor Set

		Modified Cope Suture Anchor K873606		Enterostomy Suture Anchor Set Subject Device	
Regulation Number		876.5010		876.5980	
Product Code		FGE		KGC	
Classification		II		II	
Intended Use		Used for retaining hollow viscera prior to introduction of interventional catheters		Intended for anchoring the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters and stay in place for up to 14 days in child, adolescent, and adult populations	
Device Picture					
Anchor	**Material**	Stainless Steel (T-302 or T-304)		Stainless Steel (T-304)	
	Dimensions	**Diameter**	**Length**	**Diameter**	**Length**
		0.038 in	2 cm	0.025 in	1.3 cm
	Count	1		2 (both anchors loaded in backload needle)	

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

		Modified Cope Suture Anchor K873606		Enterostomy Suture Anchor Set Subject Device	
Suture	**Material**	Polydek® suture		Tevdek® suture	
	USP Size	4-0		5-0	
	Length	40 cm		30 cm	
	Count	1		Identical (1 per anchor)	
	Proximal suture needle	Yes		No	
Introducer needle	**Material**	Stainless Steel		Stainless Steel	
	Material, hub	Polycarbonate		Polycarbonate	
	Distal tip	Lancet		Identical	
	Dimensions	**Diameter**	**Length**	**Diameter**	**Length**
		18 G	12 cm	18 G	7 cm
Backload needle	**Material**	Not included		Stainless Steel	
	Distal tip			Blunt	
	Dimensions			**Diameter**	**Length**
				18 G	5 cm
Wire guide	**Material**	Stainless Steel (T-302 or T-304)		Stainless Steel (T-304)	
	Distal Tip	Flexible		Identical	
	Coating	Not coated		Polytetrafluoroethylene	
	Dimensions	**Diameter**	**Length**	**Diameter**	**Length**
		0.038 in	80 cm	0.035 in	80 cm
Dilator	**Material**	Not included		Polyethylene	
	Distal Tip			Tapered	
	Dimensions			**Diameter**	**Length**
				8 Fr	20 cm
Indwell period		10-14 days		Up to 14 days	
Suture securement method		Secured to skin		Wrap the ends of the suture around gauze rolls and secure in place	
Mode of operation		Loaded anchor is deployed into the stomach with the wire guide from the proximal end of the introducer needle. After the tract formation, the anchor is removed by cutting the suture and allow their passage via the gastrointestinal system.		Identical	
One-time Use		Yes		Identical	
Sterilization, SAL		ETO, 10^{-6}		Identical	
Packaging		Tyvek peel-open pouch		Identical	

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Technological Characteristics:

The subject devices, Cope Pediatric Gastrointestinal Suture Anchor Set and Enterostomy Suture Anchor Set, were subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Bench Testing (including time zero and applicable three year accelerated aged testing)

- Visual Inspection, Compatibility, and Dimensional Verification Testing (Zero Time and Accelerated Aged)
- Tensile Testing (Time Zero and Accelerated Aged)
- MR Testing (Time Zero)
- Radiopacity Testing (Time Zero)

Biocompatibility Testing:

Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity, were performed on the subject device to ensure the biocompatibility of the subject device. Additional testing was performed on the suture anchors: testing for subacute/subchronic toxicity, genotoxicity, and implantation.

Sterility and Packaging

- Finished Product Qualification – Sterility, Bioburden, Endotoxin, and EO Residual
- Simulated Distribution Testing

Conclusion:

The results of these tests confirm that the Cope Pediatric Gastrointestinal Suture Anchor Set and Enterostomy Suture Anchor Set meet the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device, the Modified Cope Suture Anchor (K873606, Cook Incorporated).