May 17, 2019

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

Re: K191015
Trade/Device Name: Soft-Pass™ Embryo Mock Transfer Catheter Sets (Soft-Pass™ Embryo Mock Transfer Catheter Set and Soft-Pass™ Embryo Mock Transfer Catheter Set with Echogenic Tip)
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: Class II
Product Code: MQF
Dated: April 16, 2019
Received: April 17, 2019

Dear Ian Herrman:

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Sharon M. Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K191015

Device Name
Soft-Pass™ Embryo Mock Transfer Catheter Sets (Soft-Pass™ Embryo Mock Transfer Catheter Set and Soft-Pass™ Embryo Mock Transfer Catheter Set with Echogenic Tip)

Indications for Use *(Describe)*

The Soft-Pass™ Embryo Mock Transfer Catheter Sets are used for mock (simulated) embryo transfer procedures to aid in verifying catheter access and positioning in advance of an embryo transfer procedure.

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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510(k) SUMMARY
K191015
Soft-Pass™ Embryo Mock Transfer Catheter Sets

Submitted By:

Applicant:	Cook Incorporated
Contact:	Ian Herrman
Applicant Address:	750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	(812) 339-2235 x104034
Contact Fax Number:	(812) 332-0281

Date Prepared: May 15, 2019

Device Information:

Trade Names:	Soft-Pass™ Embryo Mock Transfer Catheter Sets (Soft-Pass™ Embryo Mock Transfer Catheter Set and Soft-Pass™ Embryo Mock Transfer Catheter Set with Echogenic Tip)
Common Name:	Assisted Reproduction Catheter
Regulation Number:	21 CFR §884.6110
Regulation Name:	Assisted Reproduction Catheters
Product Code:	MQF – Catheter, Assisted Reproduction
Device Class:	II

Predicate Device:

K173103 - Pivet and Soft-Pass Embryo Transfer Catheter Sets. Specifically, the Soft-Pass Embryo Mock Transfer Catheter Sets cleared in the predicate submission.

The predicate devices have not been subject to a design-related recall.

Device Description

The Soft-Pass Embryo Mock Transfer Catheter Sets are used to aid in verifying access and positioning of embryo transfer catheters prior to placing transfer catheters containing embryos into the uterine cavity. These devices consist of a polyethylene guide catheter that is 6.8 Fr in diameter and either 12 or 17.3 cm long, and a polyethylene mock transfer catheter that is 4.4 Fr in diameter and 19.7 or 24.7 cm long. The tip of the mock transfer catheter is closed. The echogenic tip versions of the device also include an echogenic stainless steel band on the distal tip of the mock transfer catheter to aid in tip visualization when using ultrasound. The echogenic tip versions also include a supporting stainless steel cannula in the proximal portion of the mock transfer catheter. Depth markers are also included on both the guide and mock transfer catheters to aid in placement of the device during a mock procedure. These devices are sterilized by

ethylene oxide, single-use only, and have a three-year shelf-life. The product number and trade name for the subject device sets are presented in the table below.

Model Number	Trade Name
J-SPPE-681200-MC	Soft-Pass™ Embryo Mock Transfer Catheter Set
J-SPPE-681700-MC	Soft-Pass™ Embryo Mock Transfer Catheter Set
J-SPPE-681210-ET-MC	Soft-Pass™ Embryo Mock Transfer Catheter Set with Echogenic Tip
J-SPPE-681710-ET-MC	Soft-Pass™ Embryo Mock Transfer Catheter Set with Echogenic Tip

Indications for Use

The Soft-Pass™ Embryo Mock Transfer Catheter Sets are used for mock (simulated) embryo transfer procedures to aid in verifying catheter access and positioning in advance of an embryo transfer procedure.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:

		Predicate Device	Subject Device
		Pivet and Soft-Pass Embryo Transfer Catheter Sets	**Soft-Pass Embryo Mock Transfer Catheter Sets**
510(k) Number		K173103 (Specifically, the Soft-Pass Embryo Mock Transfer Catheter Sets with a polyethylene guide catheter, J-SPPE-68XXXX-MC[-ET])	Subject of this submission
Indications for Use		The Embryo Transfer Catheters/Sets are used for transferring IVF embryos into the uterine cavity.	The Soft-Pass™ Embryo Mock Transfer Catheter Sets are used for mock (simulated) embryo transfer procedures to aid in verifying catheter access and positioning in advance of an embryo transfer procedure.
Material Specification			
Transfer Catheter		Polyethylene, stainless steel (echogenic tip versions only), marker ink	Identical
Guide Catheter		Polyethylene, marker ink	Identical
Physical Characteristics			
Hub		Flared hub on the guide catheter	Identical
Dimensional Data			
Transfer Catheter	**OD**	4.4 Fr	Identical
	Length	19.7 cm to 24.7 cm	Identical
Guide Catheter	**OD**	6.8 Fr	Identical
	Length	12 cm to 17.3 cm	Identical
Physical Features			
Transfer		With graduation marks	Identical
		No end-hole	Identical

	Predicate Device	Subject Device
	Pivet and Soft-Pass Embryo Transfer Catheter Sets	**Soft-Pass Embryo Mock Transfer Catheter Sets**
	With or without Echotip	Identical
Guide	With graduation marks	Identical
	Without positioner	Identical
	Without Echotip	Identical
	Straight	Identical
Manufacturing Features		
Sterilization	ETO	Identical
Packaging	Tyvek Sterile Barrier	Identical
Shelf Life	3 years	Identical

The purpose of this submission is to modify the indications statement for the Soft-Pass Embryo Mock Transfer Catheter Sets to clarify the cleared uses of these devices. As shown in the table above, the subject and predicate devices have different indications for use statements; however, the intended uses of the predicate and subject devices are the same (i.e., catheter used to aid in embryo transfer procedures).

In regards to technological characteristics, the subject Soft-Pass Embryo Mock Transfer Catheter Sets are identical to those cleared under K173103. Therefore, there are no differences raising different questions of safety or effectiveness.

Performance Data:

The subject device, Soft-Pass Embryo Mock Transfer Catheter Sets, are identical to those cleared under K173103 and have not undergone any design changes since clearance. The changes in indications for use included in this submission did not require additional performance testing. Therefore, the performance testing included in K173103 supports the Soft-Pass Embryo Mock Transfer Catheter Sets included in this submission.

Conclusion:

The Soft-Pass Embryo Mock Transfer Catheter Sets are substantially equivalent to the predicate devices.