DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 28, 2016

Cook Incorporated
Ms. Erum Nasir
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K161002
Trade/Device Name: Aprima Smartesis Centesis Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: August 31, 2016
Received: September 2, 2016

Dear Ms. 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 Part 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 Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K161002

Device Name
Aprima Smartesis™ Centesis Pump

Indications for Use *(Describe)*
The Aprima Smartesis™ Centesis Pump is a motorized pump to be used in conjunction with the appropriate disposable Aprima Smartesis™ Centesis Collection Tray for paracentesis drainage procedures.

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

Aprima Smartesis™ Centesis Pump (21 CFR §878.4780)
Date Prepared: August 31, 2016

Submitted By:

Applicant:	Cook Incorporated
Contact:	Erum B. Nasir
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:	Aprima Smartesis™ Centesis Pump
Common Name:	Powered suction pump
Classification Name/Panel:	Pump, Portable, Aspiration (Manual or Powered) - General & Plastic Surgery
Regulation	21 CFR §878.4780
Product Code	BTA

Predicate Device:

- RenovaRP™ Paracentesis Pump (GI Supply, K970186)

Device Description:

The Aprima Smartesis™ Centesis Pump is a portable, reusable peristaltic suction pump designed for paracentesis procedure in a manner that is both rapid and convenient. The Aprima Pump is comprised of one pump, one power cord, and operating instructions. The Aprima Pump employs peristaltic pump technology to provide displacement of fluid through the centesis tubing set, a component of the Aprima Smartesis Centesis Tray. Operation of the Aprima Pump is initiated with a control knob on the front panel. The Aprima Pump is equipped with a variable speed control of the rollers, thus allowing the operator to control the rate at which the fluid is withdrawn from the patient.

The Aprima Pump is to be used with the Aprima Smartesis™ Centesis Collection Tray only, which includes the needle for access to the abdominal cavity and the connecting tube with attached drainage bags for removal of the fluid during treatment. The Aprima Smartesis™

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Centesis Collection Tray and Bags are not included with the Aprima Pump and are packaged and sold individually. No tools are required to load or to remove the tubing and drainage bags.

Intended Use:

The Aprima Smartesis™ Centesis Pump is a motorized pump to be used in conjunction with the appropriate disposable Aprima Smartesis Centesis Collection Tray for paracentesis drainage procedures.

Comparison to Predicates:

The Aprima Pump is substantially equivalent to the predicate device, the RenovaRP™ Paracentesis Pump. The devices have the same intended use, operating mechanism, basic design, portability, and function. The minor differences between the subject and the proposed device are presented in the following table and are listed as dimension, weight, input current/voltage, maximum vacuum, AC power operations, and safety features. These minor differences were appropriately assessed and do not raise new questions regarding safety or effectiveness. In addition, the testing performed demonstrates that the proposed device meets the applicable electrical safety requirements, electromagnetic compatibility requirements, and has comparable performance as compared to the predicate device. The comparison table is listed below,

Device	**RenovaRP™ Paracentesis Pump (K970186)**	**Aprima Smartesis™ Centesis Pump (Proposed device)**
Regulation	21 CFR §878.4780	21 CFR §878.4780
Classification	Class II	Class II
Product code	BTA - Pump, Portable, Aspiration (manual or powered)	BTA - Pump, Portable, Aspiration (manual or powered)
Intended Use	The GI Supply RenovaRP™ Paracentesis Pump is intended as a suction pump to remove ascitic fluid from the abdominal cavity in conjunction with the GI Supply Paracentesis Kit.	The Aprima Smartesis™ Pump is a motorized pump to be used in conjunction with the appropriate disposable Aprima Smartesis™ Collection Tray for paracentesis drainage procedures.
Duration of use	Reusable	Identical
Dimensions	13 x 9 x 13 in (33 x 23 x 33 cm)	10 x 6.8 x 6.3 in (25.6 x 17.2 x 16.0 cm)
Weight	8.5 lbs (3.9 kg)	12.5 lbs (5.7 kg)
Input current	2.5A	2.0A
Input Voltage	100/230V	115/230V
Input Frequency	50/60Hz	Identical
Power Cord	Hospital Grade power cord	Identical
Energy used	AC-powered	Identical

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Device		**RenovaRP™ Paracentesis Pump (K970186)**	**Aprima Smartesis™ Centesis Pump (Proposed device)**
Type of pump		Peristaltic	Identical
Maximum measured vacuum (kPa)		-94.2 (used with 7Fr cannula)	-85.7 (used with 5Fr needle) -88.9 (used with 4Fr needle)
Pressure Control		Not controlled	Identical
Speed control		Dial	Identical
Filter		No	Identical
AC power operation		AC power switch is part of the dial	AC on and off switch
Handle for transporting pump		Yes, portable	Identical
Safety features	**Usability**	Safety guard, but device can be run while open.	Door acts as a movable guard that prevents use while open, One-direction flow (clips in the tubing set prevent incorrect installation).
	Electrical	Safety ground	Grounded enclosure

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified testing parameters. These tests include:

1. Electrical Safety Testing – Cook Inc. holds the UL certificate for the Aprima Pump. The UL certificate shows that the Aprima Pump complies with the requirements of IEC 60101-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*. Tests covered by UL certificate include:
    - Leakage Currents Test
    - Dielectric Strength Test
    - Creepage Distances Test
    - Spillage Test
    - Push Test
    - Impact Test
    - Drop Test
    - Grip/handle Strength Test
    - Movable Guards Test
    - Audible Acoustic Energy Test
    - Maximum Temperature Test during Normal Use
    - Instability Test
    - Firmware Verification

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2. Electromagnetic Compatibility – Testing was performed to show the device conforms to the requirements of IEC 60101-1-2 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*, including:
    - Harmonic Current Emission
    - Voltage Fluctuations and Flicker
    - Power Line Conducted Emissions and Radiated Emissions
    - Electrostatic Discharge Immunity
    - Electrical Field Radiated Immunity
    - Electrical Fast Transient/Burst Immunity
    - Surge Immunity
    - Conducted Immunity
    - Magnetic Field Immunity
    - Voltage Dips, Short Interruptions and Voltage Variations Immunity
3. Performance Testing
    - Simulated Use – Testing was conducted to obtain clinical opinions on the use of the Aprima Smartesis™ Centesis Pump and Collection Tray. All users were able to use provided components to successfully perform the centesis procedure in accordance with the intended use statement and the predetermined acceptance criteria for this study were met.
    - Characterization of Flowrate and Pressure at Different Speed Settings for the Aprima Smartesis™ Centesis Pump and the RenovaRP™ Paracentesis Pump – Testing was performed to characterize the flowrate and pressure for the proposed pump and the predicate pump.
    - Life Cycle Cleaning Test – Testing was performed to show that the Aprima Smartesis™ Centesis Pump did not exhibit degradation of electrical safety after the simulation of 1 year life cycle of cleaning. The predetermined acceptance criterion was met.
    - Wipe Test of Various Labels – Testing was performed to show that the pump labeling shall be legible after the required number of cleaning cycles. The predetermined acceptance criterion was met.
    - Aprima Smartesis™ Centesis Pump Distribution Testing – Testing was performed to show that pump functions correctly without visible damage before and after

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distribution cycle testing in packaging. The predetermined acceptance criterion was met.

Conclusion:

The results of these tests support a conclusion that the Aprima Smartesis™ Centesis Pump met 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. The Aprima Smartesis™ Centesis Pump is substantially equivalent to the RenovaRP™ Paracentesis Pump (GI Supply, K970186).