March 13, 2020

ProSys International Ltd
Graham Steer
R&D Director
Suite 303, Highland House
165 The Broadway
SW19 1NE Wimbledon, Loudon
UNITED KINDOM

Re: K193325
Trade/Device Name: Avantgarde Faecal Management Systems
Avantgarde Faecal Management System Replacement Pouches
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: February 13, 2020
Received: February 19, 2020

Dear Graham Steer:

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/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, PhD
Acting Assistant 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)*
K193325

Device Name
Avantgarde Faecal Management System
Avantgarde Faecal Management System Replacement Pouches

Indications for Use *(Describe)*

The Avantgarde Faecal Management System (FMS) is intended for faecal management by the collection of semi liquid or liquid faecal matter in bedridden adults.

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.

510(k) SUMMARY

In accordance with 21 CFR 807.92 and the Safe Medical Devices Act 1990, the following information is provided for the Avantgarde Faecal Management System 510(k) Premarket Notification. This submission was prepared in accordance with the FDA Guidance Document "Format for Traditional & Abbreviated 510(k)s'

Subject Device(s): Avantgarde Faecal Management System
Avantgarde Faecal Management System Replacement Pouches

Date Prepared: 1st December 2019

Applicant:
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Contact:
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Device Trade Name: Avantgarde Faecal Management System

Classification Name: Gastrointestinal tube and accessories

Product Code: KNT

Regulation: CFR 876-5980

Device Class: Class II

PREDICATE DEVICES:

Legally marketed Medical Devices to which Substantial Equivalence is claimed:

Trade Name: Flexi-Seal Signal
Manufacturer: ConvaTec Inc
510(k) Substantial Equivalence: K150350 – See FDA Approval in Section 31
Determined Substantially Equivalent: 21st July 2015

DEVICE DESCRIPTION

The Avantgarde Faecal Management System (catheter) is an invasive medical device to be used inside the body. It consists of a silicone catheter tube with inflation cuff and irrigation port, a 1,500ml collection bag, mounting plate with an attachment strap and 45ml syringe. This tray of devices, is supplied as a Convenience Kit. In addition, other related medical devices to enable the Avantgarde work effectively, include the Avantgarde Faecal Management System Replacement Pouches which are to be supplied on a bundle basis.

This non-sterile device is for single use only.

The FMS catheter tube is constructed of a silicone material. The balloon once inflated retains the device in the rectum. The liquid or semi-liquid stool is diverted into the drainage tube, which provides a route for the liquid or semi-liquid faecal matter to pass into the collection bag.

Along the tube are two lumens with individual access ports. One port to inflate and deflate the balloon and the other to add water to flush and irrigate the catheter tube.

Its shelf life is 5 years from the date of production.

INTENDED USE

The Avantgarde Faecal Management System is intended for faecal management by the collection of semi-liquid or liquid faecal matter in bedridden adults.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The following table which forms part of this 510(k) submission contains a very brief summary of the technological characteristics of Avantgarde Faecal Management System compared to the predicate device. This table is supported by additional information in **section 30** (Substantial Equivalence Discussion) and the Executive Summary **section 28**.

Function	Avantgarde Faecal Management System	ConvaTec Flexi Seal Signal FMS	Similarities
Intended Use	Faecal Management	Faecal Management	Both devices are the same
Animal Derived Material Content	None	None	Both devices are the same
Sterility	Non Sterile	Non Sterile	Both devices are the same
Medical Device Class	Class II	Class II	Both devices are the same
Inflation Port	Pressure Release Valve	Luer	Avantgarde is provided with a pressure release valve to ensure the balloon/cuff can not physically be over inflated.
Irrigation Port	Luer	Luer	Both devices are the same
Collection Bag	1,500ml Silicone Disposable Bags	1,000ml Disposable Collection Bags	Avantgarde has a larger collection capacity but they are basically similar
Catheter Tube Length	1,700mm	1,550mm – 1,670mm	Avantgarde is slightly longer but they are basically similar
Device Material	Constructed of Silicone with Parylene coating	Silicone Rubber	Avantgarde has an enhanced waste fecal flow rate but they are basically the same

SUMMARY OF PERFORMANCE (NON CLINICAL TESTING) DATA

Non clinical testing of the subject device for functional and structural characteristics has been performed. In the testing, the device was found to be substantially equivalent to the predicate device. Typical testing included F1980 Standards guide for accelerated aging of sterile medical device package; F 88 Standard test method for seal strength of flexible barrier materials; F1929 Standard test method for detecting seal leaks in porous medical packaging by dye penetration; ASTM D 4169 Standard practice for performance testing of shipping containers and systems; W-ZK-08-65 Final Inspection criteria for faecal management system: ISO8669-2 Urine collection bags-part 2: Requirements and test methods.

In addition Avantgarde Faecal Management Systems had been tested against ISO 10993 by Soochow University and it confirms that Avantgarde is non-toxic.

In conclusion, the subject device (Avantgarde) has been shown to be as safe and effective and substantially equivalent to the predicate devices.

END