DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 28, 2016

RanD S.r.l.
Simone Ceretti
Regulatory Affairs Manager
via Statale 12, 62
Medolla 41036
ITALY

Re: K161613
Trade/Device Name: Hang&Go PAC
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LGZ
Dated: November 25, 2016
Received: December 1, 2016

Dear Simone Ceretti:

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 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.

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,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
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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)*
K161613

Device Name
Hang&Go PAC

Indications for Use *(Describe)*
Disposable device intended to recirculate, filtrate and perfuse physiologically compatible sterile solution (i.e. saline solution) in the thoracic or abdominal cavity. The device is intended for use in a single 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

21 CFR 807.92(a)(1): Submitter and Manufacturing site information

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Establishment registration number: 3003793891

Date of the present summary preparation: 28th December, 2016

21 CFR 807.92(a)(2): Device information

Trade name:	Hang&Go PAC
Device:	Infusion pump
Classification Panel:	General Hospital
Product Code:	LGZ (Warmer, Thermal, Infusion Fluid)
Regulation name:	Infusion pump
Regulation number:	21 CFR § 880.5725
Regulatory Class:	2

21 CFR 807.92(a)(3): Predicate device

Hang&Go HT Basic (cleared under K120026, dtd. May 8 2012).

21 CFR 807.92(a)(4): Description of the device

The Hang&Go PAC is intended to be used like the Hang&Go HT Basic R9900090, cleared under K120026. The Hang&Go PAC, just like the Hang&Go HT Basic, is a disposable, single use kit intended to circulate and filtrate physiologically compatible sterile solution (i.e. saline solution) in the thoracic or abdominal cavity. The Hang&Go PAC is supplied sterile and packaged in a proprietary-design container and it is intended to be used only with the PERFORMER HT.

The Hang&Go PAC, just like the Hang&Go HT Basic, includes all necessary tubing and components for the treatment execution:

- circulation tubing
- heater bag
- reservoir
- table pack (Patient inlet and outlet tubing) with thermal protections

21 CFR 807.92(a)(4): Description of the device (Flow Reverse)

The Flow Reverse is a disposable, sterile component of the Hang&Go PAC. It is supplied sterile, individually packaged and included in the Hang&Go PAC carton box. The crossed layout of the 4 tubing segments allow to exchange the Patient's inlet and outlet flows by selectively opening / closing two segments at a time with the provided manual clamps.

21 CFR 807.92(a)(5): Indications for use
The Hang&Go PAC is a disposable device intended to recirculate, filtrate and perfuse physiologically compatible sterile solution (i.e. saline solution) in the thoracic or abdominal cavity.
The device is intended for use in a single procedure.

Predicate device intended use
The Hang&Go HT Basic is a disposable device intended to recirculate, filtrate and perfuse clear solutions in the thoracic or abdominal cavity.
The device is intended for use in a single procedure.

21 CFR 807.92(a)(6): Comparison of technological characteristics
The Hang&Go PAC has the same intended, materials and principle of use of the Hang&Go HT Basic.
The design of the Hang&Go PAC differs from the Hang&Go HT Basic in the following aspects:

- The inlet and outlet tubing to/from the Patient of the Hang&Go PAC have two access points, instead of three;
- The inlet and outlet tubing of the Hang&Go PAC have two additional integrated temperature probes;
- The inlet and outlet tubing of the Hang&Go PAC have pre-assembled catheters, instead the Hang&Go HT Basic inlet and outlet tubing have proper connectors at one end ant the user must connect catheters at the moment of use;
- the Hang&Go PAC includes in the packaging an accessory, the Flow Reverse. Comparison with this component is detailed in the following section.

Manufacturing process for the assembly of the components and the sterilization process are the same conducted on the Hang&Go HT Basic. Moreover, main technical features and mode of use are the same. Thus, all the validation activities made on the Hang&Go HT Basic (mechanical tests, efficacy tests, shelf life, compatibility, validation of sterilization process and microbiological controls) apply to the Hang&Go PAC too.

21 CFR 807.92(a)(6): Comparison of technological characteristics (Flow Reverse)
As said above, the Flow Reverse is a component included into the Hang&Go PAC packaging. The Flow Reverse is made of elements (i.e. tubing, quick connectors, Y connectors, manual clamps) already used for the Hang&Go HT Basic manufacture.
Manufacturing process for the assembly of the components and the sterilization process are the same conducted on the Hang&Go HT Basic.

21 CFR 807.92(b)(1): Discussion of the non-clinical tests
The table below lists all standards to which the Hang&Go PAC is compliant.
Biocompatibility and sterilization are covered by the testing and validation done on the Hang&Go HT Basic.
Packaging qualification acc. to ASTM D4169 and accelerated aging test acc. to ASTM F1980 were instead repeated using the same protocols of the Hang&Go HT Basic, and force at break of the pre-assembled catheters acc. to EN 1617 (not applicable to the Hang&Go HT

Basic) was also conducted. The biocompatibility and sterilization verification testing associated with the standards listed below were applied to the predicate device and cross referenced to support the substantial equivalence of the Hang&Go PAC and Reverse Flow components.

Table 1: Applicable Reference Standards list

Area	US Recognized standard #	Title
General	ISO 14971:2007	Medical devices - Application of risk management to medical devices
Packaging and labeling	ASTM D4169-14	Standard Practice for Performance Testing of Shipping Containers and Systems
Biocompatibility	AAMI ANSI ISO 10993-1:2009/(R)2013	Biological evaluation of medical devices - Part 1: Evaluation and testing
		Biological evaluation of medical devices - - Part 4: Selection of tests for interactions with blood
	AAMI ANSI ISO 10993-5:2009/(R)2014	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
	AAMI ANSI ISO 10993-7:2008/(R)2012	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
	AAMI ANSI ISO 10993-11:2006/(R)2010)	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
Sterility	ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
	ISO 11607-1:2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
	ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	ASTM F1980-07(2011)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
	ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods-Part 1: Determination of the population of microorganisms on product

In addition, the following tests (they do not follow any reference standard method) were conducted using saline solution to demonstrate continued conformance of new design outputs with the defined requirements:

- Static priming volume of the Hang&Go table pack inlet/outlet lines;
- Qualification of the two additional temperature probes assembled on the table pack lines;

- Pressure drops determination of the Hang&Go table pack inlet/outlet lines;
- Verification of the fitting interfaces and effectiveness of the Flow Reverse.
- Physical integrity verification through hydraulic test in pressure of the Flow Reverse
- Static and Dynamic Priming Volume of the Flow Reverse.

21 CFR 807.92(b)(1): Discussion of the non-clinical tests (Flow Reverse)
As said, the Flow Reverse uses the same components already in use in the Hang&Go HT Basic. Manufacturing process, sterilization, and packaging are also the same. All above listed reference standards apply also to the Flow Reverse (except EN 1617 being specifically related for the catheters, preassembled to the Hang&Go PAC table pack lines). All testing and validations for packaging, sterilization and biocompatibility conducted on the Hang&Go HT Basic apply to the Hang&Go PAC and the Flow Reverse too.
The tests listed in the last 3 bullet points of the previous paragraph were conducted on the Flow Reverse for qualification of the related features. The protocols used in these tests were similar to those used for qualifying the same features of the Hang&Go HT Basic. Saline was used as the test liquid to represent the physiologically compatible sterile solution.

21 CFR 807.92(b) (3): Conclusions
Based upon performance testing and compliance with voluntary standards, RanD believes that the Hang&Go PAC is substantially equivalent to the predicate device, and does not raise new concerns of safety or effectiveness.