April 19, 2023

GI Supply, Inc.
Thomas Saladin
Global Regulatory Lead
5069 Ritter Road Suite 104
Mechanicsburg, Pennsylvania 17055

Re: K221042
Trade/Device Name: Renova RP Centesis Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: March 20, 2023
Received: March 20, 2023

Dear Thomas Saladin:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.04.19 08:38:23 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221042

Device Name
RenovaRP® Centesis Pump System

Indications for Use *(Describe)*
The RenovaRP® Centesis Pump is intended to be used in conjunction with the RenovaRP Tube Set and the RenovaRP Fluid Drainage Bags to remove ascitic fluid from the abdominal cavity for paracentesis, and remove pleural effusion from the thoracic cavity for thoracentesis.
The Renova RP Centesis Pump is intended to be used by medically trained healthcare professionals knowledgeable about paracentesis and thoracentesis.

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

I.SUBMITTER/510(k) SPONSOR

Sponsor/Manufacturer
GI Supply, Inc.
5069 Ritter Road
Suite 104
Mechanicsburg, PA 17055 USA
Phone: (800)-451-5797

Contact Person
Thomas Saladin
Sr. Regulatory Affairs Specialist
Phone: (952)-471-6665
Email: tsaladin@laborie.com

Alternate Contact
Meghan Moore
Manager Regulatory Affairs
Email: mmoore@laborie.com

Preparation Date
April 14, 2023

II. DEVICE NAME/CLASSIFICATION

Device Trade/Proprietary Name	RenovaRP® Centesis Pump System
Device Common or Usual Name	Suction Pump, Peristaltic Pump
Device Regulatory Classification	Class II
Device Classification Regulation	21 CFR 878.4780
Product Code	BTA
Submission Type	Traditional 510(k)
Classification Panel	General & Plastic Surgery

III. PREDICATE DEVICE

K970186, RenovaRP® Paracentesis Pump System

IV. DEVICE DESCRIPTION

The RenovaRP® Centesis Pump is intended to be used in conjunction with the RenovaRP® Tube Set and RenovaRP® Fluid Drainage Bags (provided separately from the pump) to remove fluid from the abdominal cavity for paracentesis, and pleural effusion from the thoracic cavity for thoracentesis.

V. INTENDED USE / INDICATIONS FOR USE

Intended Use / Indications for Use

The RenovaRP® Centesis Pump is intended to be used in conjunction with the RenovaRP Tube Set and the RenovaRP Fluid Drainage Bags to remove ascitic fluid from the abdominal cavity for paracentesis, and remove pleural effusion from the thoracic cavity for thoracentesis.
The Renova RP Centesis Pump is intended to be used by medically trained healthcare professionals knowledgeable about paracentesis and thoracentesis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The detailed substantial equivalence comparison of the similarities and differences between the RenovaRP® Centesis Pump System [subject device] and the RenovaRP® Paracentesis Pump (K970186) [predicate device] is provided in the table below. Please note that the devices have the same manufacturer, and only differ with regard to indications for use and proprietary/trade name. The fundamental design and operational and technological characteristics of the subject device remain the same.

No performance data was needed to evaluate the expansion of the indications for use to include thoracentesis. The change of the subject device's indications does not increase risks or impact safety or effectiveness when compared to the predicate device.

Regulatory Information	[Subject Device]	[Predicate Device]	Similarities / Differences
Manufacturer	GI Supply, Inc.	GI Supply, Inc.	Same
Device Trade or Proprietary Name	RenovaRP® Centesis Pump System	RenovaRP® Paracentesis Pump	Different
510(k) Number	K221042	K970186	---
Device Class	Class II	Class II	Same
Device Classification Name	General & Plastic Surgery	General & Plastic Surgery	Same
Device Common Name	Pump, Portable, Aspiration (Manual or Powered)	Pump, Portable, Aspiration (Manual or Powered)	Same
Product Code	BTA	BTA	Same
Regulation Number	21 CFR 878.4780	21 CFR 878.4780	Same
Design Features and Capabilities of the Device			
Indications for Use	The RenovaRP® Centesis Pump is intended to be used in conjunction with the RenovaRP Tube Set and the RenovaRP Fluid Drainage Bags to remove ascitic fluid from the abdominal cavity for paracentesis, and remove pleural effusion from the thoracic cavity for thoracentesis. The Renova RP Centesis Pump is intended to be used by medically trained healthcare professionals knowledgeable about paracentesis and thoracentesis.	The RenovaRP® Paracentesis Pump is intended as a peristaltic pump to remove ascitic fluid from the abdominal cavity in conjunction with the RenovaRP® Paracentesis Kit. The RenovaRP® Paracentesis Pump is intended to be used by medically trained healthcare professionals knowledgeable about paracentesis.	Different
Intended Use	Suction pump for removal of fluids	Suction pump for removal of fluids	Same
Prescription or Over-the-Counter (OTC) Use	Prescription Use	Prescription Use	Same
Use Environment	Hospital / Clinic	Hospital / Clinic	Same

Regulatory Information	[Subject Device]	[Predicate Device]	Similarities / Differences
Sterile	Pump is non-sterile. Disposable components are sterile.	Pump is non-sterile. Disposable components are sterile.	Same
Disposable versus Non-Disposable	Pump is reusable. Disposable components are single patient use.	Pump is reusable. Disposable components are single patient use.	Same
Pump Physical Specifications	13x9x13 in (33x23x33 cm) 8.5 lbs (3.9kg)	13x9x13 in (33x23x33 cm) 8.5 lbs (3.9kg)	Same
Pump Power	AC only model	AC only model	Same
Pump Input Voltage	100-230V	100-230V	Same
Pump Input Current	2.5A	2.5A	Same
Pump Input Frequency	50/60Hz	50/60Hz	Same
Flow Rate	700 mL/min	700 mL/min	Same
Pump Electrical Requirements	Class I, Type B	Class I, Type B	Same
Packaging	Pump is placed in a polybag in between a top foam and bottom foam insert prior to placement in a 200# shipper box. Power cord and IFU are placed in a polybag on top of the pump under a foam cap prior to box closure. Disposable components are provided separately from the pump. Tube sets are individually sterile packaged, with each 200# shipper box containing five (5) tube sets and one (1) IFU. Bags are individually sterile packaged, with each 200# shipper box containing 20 bags. No IFU for the collection bags is required.	Pump is placed in a polybag in between a top foam and bottom foam insert prior to placement in a 200# shipper box. The power cord and IFU are placed in a polybag on top of the pump under a foam cap prior to box closure. Disposable components are provided separately from the pump. Tube sets are individually sterile packaged, with each 200# shipper box containing five (5) tube sets and one (1) IFU. Bags are individually sterile packaged, with each 200# shipper box containing 20 bags. No IFU for the collection bags is required.	Same
Shelf Life	The pump has an expected service life of 7-10 years. Tube sets have a shelf life of 24 months, while the fluid drainage bags have a shelf life of 25 months.	The pump has an expected service life of 7-10 years. Tube sets have a shelf life of 24 months, while the fluid drainage bags have a shelf life of 25 months.	Same
Regulatory Information	**[Subject Device]**	**[Predicate Device]**	**Similarities / Differences**
Manufacturer	GI Supply, Inc.	GI Supply, Inc.	Same
Design Features and Capabilities of the Device			

Regulatory Information	[Subject Device]	[Predicate Device]	Similarities / Differences
RenovaRP® Tube Set and Fluid Drainage Bags	Part of the proposed device; packaged and shipped separately as they are consumables.	N/A	The RenovaRP® Tube Set and Fluid Drainage Bags were cleared via K970187. They are the same as provided under K970187 except the revised labeling for the expanded indication to include thoracentesis. Including the tube set and fluid drainage bags as part of the RenovaRP® Centesis Pump System does not introduce new questions of safety and efficacy.

VII. SUMMARY OF PERFORMANCE DATA AND PERFORMANCE TESTING CONCLUSIONS

The RenovaRP® Centesis Pump system was evaluated using GI Supply's risk management process in accordance with ISO 14971:2019 – Medical devices – Application of risk management to medical devices. All identified risks were adequately mitigated and were previously verified by means of nonclinical performance testing.

No testing was required in support of substantial equivalence to the predicate device as the subject and predicate devices are identical in terms of device design, fundamental technology, physical characteristics, performance, and intended use. The only proposed change to the device is its indications for use, which are being expanded to include thoracentesis.

The expansion of indications did not require any additional nonclinical or clinical testing to demonstrate safety and effectiveness nor to support the substantial equivalence to the subject device; however, nonclinical bench testing is being provided as part of this submission to verify device performance and safety.

Summary of Nonclinical Performance Testing

A series of functional nonclinical performance testing was previously conducted on the RenovaRP® Centesis Pump including simulated use testing, functional testing, and distribution testing. The device was successfully evaluated for standards compliance to IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and performance and 60601-1-2 – Medical electrical equipment

– Parts 1-2, General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. Additionally, usability of the device was assessed by applying the evaluation process specified in EN IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices (Annex C, Evaluation of a user interface of unknown provenance – UOUP).

A series of functional nonclinical performance testing was previously conducted on the RenovaRP® Tube Set including simulated use testing, post-accelerated aging testing, real-time aging, biocompatibility testing (cytotoxicity, irritation, and sensitization per ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing), and distribution testing.

A series of functional nonclinical performance testing was previously conducted on the RenovaRP® Fluid Drainage Bag including graduation mark testing, post-accelerated aging testing, real-time aging, and distribution testing.

Cleaning Validation

A cleaning validation was conducted per ISO 17664, Processing of healthcare products on the RenovaRP® Centesis Pump.

VIII. CONCLUSIONS

The RenovaRP® Centesis Pump System [subject device] is substantially equivalent to the predicate device, RenovaRP® Paracentesis Pump (K970186) and its disposable components (K970187) with respect to device design, fundamental technology, physical characteristics, performance, and intended use for the removal of fluids. Device materials and packaging are identical. The disposable components are provided sterile, while both the subject and predicate pump component of the system are non-sterile, reusable, and have the same expected lifetime.