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

November 14, 2016

Rocket Medical PLC
% Tracy Charlton
Regulatory Affairs Manager
Rocket Medical PLC
2-4 Sedling Rd.
Washington, Tyne and Wear
NE38 9BZ UK

Re: K162457
Trade/Device Name: Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: Class II
Product Code: PNG
Dated: September 1, 2016
Received: September 2, 2016

Dear Tracy Charlton:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

In addition, we have determined that your device kit contains Lidocaine and DuraPrep™ which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K162457

Device Name

Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit

Indications for Use *(Describe)*

The Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit (Model # R51401-16-PT and R51401-MI-PT) contains the following MAJOR components:

- Indwelling Peritoneal Catheter (Model # ZASEM192)
- Drainage Line (Model #R54410-00-DL)
- Accessories for insertion, attachment and dressing

The Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit is indicated for intermittent drainage of symptomatic, recurrent malignant ascites. Also the palliation of symptoms related to recurrent malignant ascites.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 – 510(k) Summary

Submitter:	Rocket Medical Plc. 2-4 Sedling Road, Wear Industrial Estate Washington, Tyne and Wear NE38 9BZ UK
Contact Person:	Tracy Charlton, Regulatory Affairs Manager Phone: 00 44 191 419 4488 Ext 222 Fax: 00 44 191 416 5693 tracy@rocketmedical.com
Date Prepared:	September 1, 2016
Trade Name:	Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit
Classification:	Class II Peritoneal dialysis system and accessories 21 CFR 876.5630
Product Code:	PNG
Predicate Device(s):	The subject device is equivalent to the following device: o Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit; (Rocket Medical Plc, K152105)
Device Description:	The Rocket Indwelling Peritoneal Catheter (IPC) is a fenestrated silicone drainage catheter intended for the drainage of peritoneal ascites. The catheter has a polyester cuff for attachment to the patient and a silicone one-way valve to prevent air and fluid from migrating back into the peritoneum. The IPC Insertion Kit consists of the IPC, drainage line and accessories for insertion, attachment and dressing. In addition, the Rocket IPC Insertion Kit contains currently licensed 1% lidocaine (5 mL x 3) and DuraPrep (6 mL x 2).
Indications for Use:	The Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit (Model # R51401-16-PT and R51401-MI-PT) contains the following MAJOR components: • Indwelling Peritoneal Catheter (Model # ZASEM192) • Drainage Line (Model #R54410-00-DL) • Accessories for insertion, attachment and dressing The Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit is indicated for intermittent drainage of symptomatic, recurrent malignant ascites. Also the palliation of symptoms related to recurrent malignant ascites.

Substantial Equivalence:

Parameter	Subject Device Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit	Predicate Device Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit
510(k) Number	TBD	K152105
Classification	Class II	Same
Product Code	PNG	Same
Regulation	21 CFR 876.5630	Same
Indications for Use	The Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit (Model # R51401-16-PT and R51401-MI-PT) contains the following MAJOR components: • Indwelling Peritoneal Catheter (Model # ZASEM192) • Drainage Line (Model #R54410-00-DL) • Accessories for insertion, attachment and dressing The Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit is indicated for intermittent drainage of symptomatic, recurrent malignant ascites. Also the palliation of symptoms related to recurrent malignant ascites.	Same
Kit Components and Accessories	Identical to predicate except also contains currently licensed Lidocaine (5mL x 3) and DurePrep (6 mL x 2)	IPC Catheter, drainage line and accessories for insertion, attachment and dressing
Kits	Model # R51401-16-PT and R51401-MI-PT	Same
Performance	Resistance to deformation; force at break- connections; force at break-drainage catheters and all other parts; freedom from leakage	Same
Biocompatibility	Cytotoxicity, sensitization, irritation, system toxicity, subchronic toxicity, genotoxicity, implantation, exhaustive extraction, summary report and biological risk assessment	Same
Packaging components and materials	APET tray, blue field wrap, uncoated Tyvek 1073B/PET pouch, folding carton	Same
Sterility	SAL 10^6	Same
Sterilization Method	EtO	Same
Shelf life	3 years	Same

Functional and Safety Testing:	Because the subject device is identical to the predicate device except for the addition of the currently licensed lidocaine and DuraPrep, and no manufacturing processes or sterilization method have been changed, no new biocompatibility or shelf life testing was performed for this submission. However, packaging and sterilization validations were performed. Lidocaine was tested post sterilization per the USP monograph. DuraPrep is validated for two EtO sterilization cycles and therefore required no additional testing.
Conclusion:	Rocket Medical considers the Rocket IPC Indwelling Peritoneal Insertion Set with Lidocaine and DuraPrep to be equivalent to the predicate device listed above. This conclusion is based upon the fact that the subject device is identical to the predicate device with the exception of the addition of currently licensed lidocaine and DuraPrep in the subject device kit.