DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 29, 2016

Rocket Medical Plc
Tracy Charlton
Regulatory Affairs Manager
2-4 Sedling Rd, Wear Industrial Estate
Washington, Tyne and Wear
NE38 9BZ
United Kingdom

Re: K152105
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: February 26, 2016
Received: February 29, 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.

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,

Benjamin R. Fisher -S

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)*
K152105

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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SECTION 05: 510(K) Summary

1. INTRODUCTION

1.1 This document contains the 510(k) summary for the Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit. The content of this summary is based on the requirements of 21 CFR 807.92.

2. APPLICANT NAME AND ADDRESS:

Name: Rocket Medical Plc.
Address: 2-4 Sedling Road, Wear Industrial Estate,
Washington, Tyne and Wear
NE38 9BZ
United Kingdom
Phone: 00 44 191 419 4488
Fax: 00 44 191 416 5693

Official Contact: Tracy Charlton
Regulatory Affairs Manager

Summary Preparation Date: 24th February 2016

3. DEVICE NAME AND CLASSIFICATION

Trade Name: Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit

Common Name: Peritoneal Drainage Catheter

Classification Name: Peritoneal dialysis system and accessories

Classification: Class II, 21 CFR 876.5630

Product Code: PNG

4. PREDICATE DEVICES:

4.1 The Rocket IPC Insertion Kit is claimed to be substantially equivalent to the following legally marketed predicate devices:

4.1.1 Pleurx Peritoneal Catheter Kit and Pleurx Drainage Kits (K051711)

5. PERFORMANCE STANDARDS:

5.1 There are no mandatory performance standards for this device type.

6. DESCRIPTION OF THE DEVICE:

6.1 Rocket Medical Plc. hereby submits this Traditional 510(k) notice for its Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit. The Rocket Indwelling Peritoneal Catheter is a fenestrated silicone drainage catheter intended for the drainage of peritoneal ascites. There is 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 will consist of the

IPC and components necessary for its use such as a drainage line. In addition, the Rocket IPC is packaged into convenience kits to aid in the implantation of the Rocket IPC.

7. 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.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

8.1. The Rocket IPC insertion kit has the same intended use and the same technological characteristics as the identified predicate device. Minor difference in technological characteristics do not raise new or different questions of safety and effectiveness and validation data supports that the system performs in accordance with its intended use and is substantially equivalent to the predicate device.

8.2 The Rocket Indwelling Peritoneal Catheter (IPC) is a fenestrated silicone drainage catheter intended for the drainage of peritoneal ascites. There is 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.

8.3 The catheter insertion kit uses the option of the vacuum from a drainage bottle as a negative pressure to remove fluid from the peritoneum.

8.4 Materials: Biocompatible Silicone tubing, polyester cuff and silicone adhesive are implanted in the peritoneal space.

8.5 Sterility Assurance Level; $1x10^{-6}$

9. SUMMARY OF PERFORMANCE TESTING

9.1 Performance bench testing of the Rocket IPC was conducted in accordance with all applicable
FDA Guidance documents and ISO standards, including:

9.1.1 ISO 10993-1:2009 - *Biological evaluation of medical devices Part 1: Evaluation and Testing within a risk management process.*

9.1.2 ISO 10993-3: 2009 *Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.*

9.1.3 ISO 10993-5: 2009 *Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity*

9.1.4 ISO 10993-6: 2009 *Biological evaluation of medical devices Part 6: Tests for local effects after implantation.*

9.1.5 ISO 10993-7:2008 *Biological evaluation of medical devices Part 7: Ethylene oxide Sterilization Residuals.*

9.1.6 ISO 10993-10: 2010 *Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.*

9.1.7 ISO 10993-11: 2009 *Biological evaluation of medical devices. Tests for systemic toxicity*

9.1.8 ISO 10993-12: 2009 *Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials.*

9.1.9 ISO 10993-17: 2002 Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances

9.1.10 ISO 10993-18: 2005 Biological evaluation of medical devices -- Part 18: Chemical characterization of materials

9.1.11 ISO 11135-1:2007 *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

9.1.12 ASTM F1980- 07(2007) *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices batch testing.*

9.1.13 USP <85> *Bacterial Endotoxins Test*

9.1.14 EN 1617:1997 *Sterile Drainage Catheters and Accessory Devices for Single Use.*

9.1.15 EN 1618:1997 *Catheters Other than Intravascular Catheters – Test Methods for Common Properties.*

9.1.16 EN 868-5:2009 *Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods.*

9.1.17 ISO 15223-1:2012– *Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirement.*

9.1.18 ISO 13485:2012 *Medical devices – Quality management systems – Requirements for regulatory purposes*

9.1.19 ISO 9001:2008 *Quality management systems – Requirements*

9.2 A list of Performance Testing conducted on the Rocket IPC includes;

9.2.1 Sterilization Validation

9.2.2 Biocompatibility Validation

9.2.3 Packaging Validation

9.2.4 All bench testing, unless otherwise specified, was conducted on the finished devices, which were sterilized by the final validated sterilization process.

9.3 A Summary of Standards Based compliance testing specific for catheter devices conducted on the Rocket IPC is show in the below:

Summary of Catheter Specification Performance Testing

Test	Test Method or Standard Reference	Sample Size	Final Report	Accept/Reject Criteria	Results
Resistance to deformation	EN 1617:1997 4.2 (including Annex A)	3	NPD QA 1050	The drainage system or any component intended to operate under negative pressure shall not show deformation sufficient to impair the function of the device at the maximum negative pressure stated by the manufacturer	PASS
Force at break – Connections	EN 1617:1997 4.3.1; EN 1618: 1997 Annex F	3	NPD QA 1054 and 1055	The minimum force at break for connections shall be 15 N. (Nominal outside diameter >4mm).	PASS
Force at break – Drainage catheters and all other parts of the system	EN 1617:1997 4.3.2; EN 1618: 1997 Annex B	3	NPD QA 1054	The minimum force at break for catheter and all other parts of system shall be 20 N. (Nominal outside diameter >4mm).	PASS
Freedom from leakage – During aspiration or vacuum	EN 1617:1997 4,5; EN 1618:1997 Annex D	3	NPD QA 1051	Neither the drainage system nor any components shall leak at the maximum negative pressure stated by the manufacturer.	PASS
Impact resistance – Collection device	EN 1617:1997 4.6 (including Annex B)	3	NPD QA 1052	The collection device shall not leak	PASS
Impact – resistance – Suction Source	EN 1617:1997 4.6 (including Annex B)	3	NPD QA 1053	The suction source shall not show any loss of vacuum greater than 2%	PASS
Flow Rate	EN 1618:1997 Annex D	3	NPD QA 1053	Calculate the arithmetic average of three determinations and express it as water flow rate	PASS

				through the catheter in millilitres per minute.	

These are located in Appendix C Pages 336-406

10 SUBSTANTIAL EQUIVALENCE

10.1 Verification and validation of the Rocket IPC was performed through extensive bench testing, sterilization, packaging and shelf life testing. Results of the testing demonstrated that the Rocket IPC design met all specifications and is adequate for its intended use.

In conclusion, the Rocket IPC is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the following legally marketed predicate device:

10.1.1 Pleurx Peritoneal Catheter Kit and Pleurx Drainage Kits (K051711), manufactured by CareFusion.

10.1.2 Clinical Equivalence Justification

Refer to the table below.

Clinical Equivalence Justification

Parameter	Predicate device(s) in current use	Devices for evaluation	Gap Analysis
Description/code/ reference	Pleurx Peritoneal Catheter Kit	Rocket Medical IPC Insertion Kit	Identify reasons for an significance of differences
Essential dimensions	15.5Fg x 400mm Catheter, 500ml/1000ml Drainage Bottle	16Fg x 400mm Catheter, 600ml/1000ml Drainage Bottle	
Material specifications	Silicone, valve material, bottle material	Silicone, valve material, bottle material	None
Operating environment	Body temperature, peritoneum, subcutaneous tissue	Body temperature, peritoneum, subcutaneous tissue	None
Design concept	15.5Fg x 400mm Catheter with one way valve	16Fg x 400mm Catheter with one way valve	Despite stated differences between the catheters, the catheters measure identically and are both 5mm OD catheter with a 3mm ID. As shown in the testing documented.

Parameter	Predicate device(s) in current use	Devices for evaluation	Gap Analysis
Principles of operation	Catheter is inserted using a mixture of wire guided and tunnelled technique When insitu one way valve is opened using a specifically designed drainage bottle. The drainage bottle is pre-evacuated and the control of the level of suction is provided via a pinch clamp. This allows fluid to be drawn from the peritoneum via the catheter into the drainage bottle. When the drainage bottle is filled with fluid, the drainage is complete and the bottle is disconnected from the drainage line and discarded.	Catheter is inserted using a mixture of wire guided and tunnelled technique When insitu one way valve is opened using a specifically designed drainage bottle. The drainage bottle is pre-evacuated and the control of the level of suction is provided via a suction control valve. This allows fluid to be drawn from the peritoneum via the catheter into the drainage bottle. When the drainage bottle is filled with fluid, the drainage is complete and the bottle is disconnected from the drainage line and discarded.	The control valve was introduced over the pinch clamp to offer the end user more control over the application of vacuum and the flow of fluid. When the vacuum is applied this can cause discomfort to the patient. The vacuum control unit works by the patient pressing down a button to initiate the application vacuum. The patient can then titrate this level of vacuum to a personal level of comfort.
Method of sterilisation	EtO	EtO	None

11 RISK MANAGEMENT

11.1 Refer to Appendix D (Pages 407-416)

T. Charlton

Tracy Charlton
Regulatory Affairs Manager

24th February, 2015