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

August 17, 2017

Rocket Medical PLC
Tracy Charlton
Regulatory Affairs Manager
2-4 Sedling Rd, Wear Industrial Estate
Washington, NE38 9BZ, GB

Re: K163321
Trade/Device Name: Rocket Indwelling Pleural Catheter (IPC) Insertion Kit
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: Class II
Product Code: DWM
Dated: July 20, 2017
Received: July 21, 2017

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. 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,

Tara A. Ryan -S

for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*

K163321

Device Name

Rocket Indwelling Pleural Catheter (IPC) Insertion Kit

Indications for Use *(Describe)*

The Rocket Indwelling Pleural Catheter (IPC) Insertion Kit (Model # R51400-16-PL and R51400-MI-PL) is indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of underlying disease.

The device is indicated for:

- The palliation of dyspnea due to pleural effusion
- Providing pleurodesis (resolution of the pleural effusion)

This device should only be used by or under the supervision of trained personnel and in conjunction with current clinical practice guidelines.

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:	August 1, 2017
Trade Name:	Rocket Indwelling Pleural Catheter (IPC) Insertion Kit
Classification:	Class II Patient Care Suction Apparatus 21 CFR 870.5050
Product Code:	DWM
Predicate Device(s):	The subject device is equivalent to the following devices: o Predicate: Rocket Indwelling Pleural Catheter **(IPC)** Insertion Kit; (Rocket Medical PLC, K123033) o Reference Predicate: Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit; (Rocket Medical PLC, K162457). This device kit components and accessories are identical to the subject device. Therefore, performance is identical to the subject device.
Device Description:	Model R51400-16-PL IPC Insertion Kit consists of the IPC, drainage line and accessories for insertion, attachment and dressing. In addition, it contains currently licensed 1% lidocaine (5 mL x 3) and DuraPrep (6 mL x 2). Model R51400-MI-PL is the Mini Kit with fewer accessories and no drugs. It is for use by surgeons where the patients are already draped and insertion components are readily available. The Rocket IPC Insertion Kits are provided sterile and are for single use only. The Rocket Indwelling Pleural Catheter (IPC) is a fenestrated silicone catheter, with a barium sulfate stripe through its length, intended for the drainage of pleural effusion. 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 pleural space. This valve can only be operated with the specifically designed drainage line and drainage bottles supplied by Rocket Medical.

Indications for Use:

The Rocket Indwelling Pleural Catheter (IPC) Insertion Kit (Model # R51400-16-PL and R51400-MI-PL) is indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of underlying disease.

The device is indicated for:

- The palliation of dyspnea due to pleural effusion
- Providing pleurodesis (resolution of the pleural effusion)

This device should only be used by or under the supervision of trained personnel and in conjunction with current clinical practice guidelines.

Substantial Equivalence:

Parameter	**Subject Device Rocket Indwelling Pleural Catheter (IPC) Insertion Kit**	**Predicate Device Rocket Indwelling Pleural Catheter (IPC) Insertion Kit**	**Similarities and Differences**
510(k) Number	K163321	K123033	n/a
Classification	Class II	Same as subject device	identical
Product Code	DWM	Same as subject device	identical
Regulation	21 CFR 870.5050	Same as subject device	identical
Indications for Use	The Rocket Indwelling Pleural Catheter (IPC) Insertion Kit (Model # R51400-16-PL and R51400-MI-PL) is indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of underlying disease. This device should only be used by or under the supervision of trained personnel and in conjunction with current clinical practice guidelines.	The Rocket IPC Insertion Kit and Rocket IPC Dressing Pack and Bottle Set are indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of underlying disease. This device should only be used by or under the supervision of trained personnel and in conjunction with current clinical practice guidelines.	Same as subject device except: The bottle sets and dressing packs accessories were already cleared in the predicate (K123033); therefore, they are not part of the subject device convenience kit. However, the bottle sets and dressing packs are used with the subject device; therefore, there is no impact on substantial equivalence.

		The device is indicated for: • The palliation of dyspnea due to pleural effusion • Providing pleurodesis (resolution of the pleural effusion)	The devices are indicated for: 1. The palliation of dyspnea due to pleural effusion 2. Providing pleurodesis (resolution to the pleural effusion). The Rocket IPC Bottle Sets are indicated for use only with the Rocket Indwelling Pleural Catheter for intermittent drainage. The Rocket Dressing Packs are indicated for dressing of a catheter and exit site.	
	Kit Components and Accessories	IPC Catheter, drainage line and accessories for insertion, attachment and dressing including currently licensed Lidocaine HCl, USP (5mL x 3) and DurePrep (6 mL x 2) and four update kit accessories	IPC Catheter, drainage line and accessories for insertion, attachment and dressing	The subject device and predicate and reference predicate device insertion kits have the identical main components: indwelling catheter, drainage line and accessories for insertion, attachment and dressing. The subject device kit components including currently licensed Lidocaine HCl, USP (5mL x 3) and DuraPrep (6 mL x 2) and four updated kit accessories are identical to the reference predicate (K162457).
	Catheter and Drainage Line Technological Features	Catheter: Tubing, cuff, one-way valve and cap; Drainage line: tubing, one-way valve and locking section	Same as subject device	Since the subject device and the predicate device catheters and drainage line are identical, they have identical technological features.

	Catheter and Drainage Line Principle of Operation	Catheter is attached via the one-way valve to vacuum bottles or wall suction with drainage line for drainage of the pleural space; the one-way value on catheter or drainage line prevents air and fluid from migrating back into the pleural space	Same as subject device	Since the subject device and the predicate catheters and drainage line are identical, they have identical principles of operation.
	Catheter and Drainage Line Materials	Catheter: Silicone tubing with 30% barium sulfate stripe, polyester cuff, silicone adhesive, ABS one-way valve and cap; Drainage line: PVC tubing and ABS one-way valve and locking section	Same as subject device	Since the subject device and the predicate catheters and drainage line are identical, they have identical materials
	Kits	Model # R51400-16-PL and R51400-MI-PL	Model # R51400-16-00 and R51400-MI-PL	Unique model numbers for each device.
	Performance per EN 1617:1997 EN 1618:1997	Resistance to deformation; force at break- connections; force at break- drainage catheters and all other parts; freedom from leakage	Same as subject device	Since the main components of the devices are identical, the performance testing performed on the predicate is applicable to the subject device.
	Biocompatibility per ISO 10993-1	Cytotoxicity, sensitization, irritation, system toxicity, subchronic toxicity, genotoxicity, implantation, exhaustive extraction, summary report and biological risk assessment	Same as subject device	Since the main components of the devices are identical, the biocompatibility testing performed on the predicate is applicable to the subject device.

	Packaging components and materials	APET tray, blue field wrap, uncoated Tyvek 1073B/PET pouch, folding carton	Same as subject device	The subject device and predicate use the same packaging materials and process.
	Sterility	SAL 10^6	Same as subject device	The subject device and predicate are sterilized using the same method, the same sterility level and the same residual tesitng.
	Sterilization Method per ISO 11135-1 and ISO 10993-7	EtO and EtO residuals	Same as subject device	
	Shelf life	The shelf life will not exceed the shelf life of any of its kit components when packaged	3 years	Since the subject device is identical to the predicate except for the Lidocaine HCl, USP and DuraPrep, the stability testing on the predicate is applicable to the subject device. The shelf life of the Lidocaine HCl, USP and DuraPrep are determined and monitored by the manufacturers.

Technological and Performance Comparison:

There have been no technological modifications made to the subject device catheter or drainage line as it relates to the predicate device (they are identical), therefore the performance of the subject device catheter and drainage line is identical to the performance of the predicate device. Currently licensed Lidocaine HCl, USP and DuraPrep have been added as accessories to the Pleural IPC convenience kit, but they do not affect the technology, performance or principle of operation of the catheter and drainage line. The Lidocaine HCl, USP and DuraPrep were cleared as kit components in the Reference predicate (K162457). The Lidocaine HCL, USP was tested post EtO sterilization per the Lidocaine HCl, USP monograph and confirmed it met all Lidocaine HCl, USP monograph requirements as labeled. The DuraPrep is validated for 2 cycles of EtO sterilization by the manufacturer.

Comparison of subject device updated kit accessories to predicate and Reference predicate:

Component	Subject Device	Regulatory Status	Predicate Device	Reference Predicate
Tunneler	Metal	K152105	Plastic	Same as subject device
Suture Forceps/ Dressing Forceps	Blue tipped to signify single use	510(k) Exempt	Not blue tipped	
Needle Holder	Blue tipped to signify single use	510(k) Exempt	Not blue tipped	
Suture	Dissolvable	K981935	Silk	
Pinch Clamp and Slide Clamp	Removed from kit	N/A	Present in kit	

Summary of Performance Testing:

Because the subject device catheter and drainage line are identical to the predicate device, and no manufacturing or packaging materials or processes have changed and the sterilization method has not changed, no new performance, packaging, biocompatibility or shelf life testing was performed for this submission in order to establish substantial equivalence. Performance testing on the predicate included resistance to deformation, force at break-connections, force at break- drainage catheters and all other parts, and freedom from leakage. All testing met acceptance criteria. Biocompatibility testing on the predicate included cytotoxicity, sensitization, irritation, system toxicity, subchronic toxicity, genotoxicity, implantation, exhaustive extraction, and biological risk assessment. All testing met acceptance criteria. The shelf life will not exceed the shelf life of any of its kit components. The Lidocaine HCl, USP and DuraPrep were cleared as kit components in the Reference predicate (K162457). Lidocaine HCl, USP was tested post sterilization per the Lidocaine HCl, USP monograph and confirmed it met all Lidocaine HCl, USP requirements as labeled. DuraPrep is validated by the manufacturer for two EtO sterilization cycles and therefore required no additional testing.

Conclusion:	Rocket Medical considers the Rocket IPC Indwelling Pleural Insertion Set with Lidocaine and DuraPrep to be substantially equivalent to the predicate and Reference predicate devices listed above. This conclusion is based upon the fact that the subject device catheter and drainage line technological features, principle of operation, materials, biocompatibility, performance, packaging and sterilization are identical to the predicate. Also, all kit components including currently licensed Lidocaine HCl, USP and DuraPrep and four updated kit accessories (two cosmetic and two material changes identified in the table above: Comparison of updated kit accessories to predicate and Reference predicate) are identical and have the same shelf life as the Reference predicate. The Lidocaine HCl, USP was tested post EtO sterilization per the Lidocaine HCl, USP monograph and met all USP requirements as labeled. The difference in the Indication for Use statements of the subject and predicate as described above (exclusion of Bottle Sets and Dressing Packs for subject device) have not changed the intended use or substantial equivalence of the devices.