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Revised 510(k) K123033 SUMMARY 10th January, 2013

FEB 0 1 2013

1 INTRODUCTION:

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

2 APPLICANT NAME AND ADDRESS:

Name: Rocket Medical Plc

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Official Contact: Tracy Charlton
Regulatory Affairs Manager

Summary Preparation Date: 10th January 2013 (Revised)

3. DEVICE NAME AND CLASSIFICATION

Trade Name: Rocket Indwelling Pleural Catheter (IPC) System

Common Name: Pleural Drainage Catheter

Classification Name: Patient Care Suction Apparatus

Classification: Class II, 21 CFR 870.5050

Product Code: DWM

4. PREDICATE DEVICES:

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

4.1.1 PleurX Pleural Catheter System (K112831), manufactured by CareFusion

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 Pleural Catheter (IPC) System. The Rocket Indwelling Pleural Catheter (IPC) is a fenestrated silicone drainage catheter intended for the drainage of pleural effusions. There is a polyester cuff for attachment to the patient and a silicone one-way valve to prevent collected air and fluid from migrating back into the pleural cavity. The IPC System will consist of the IPC and components necessary for its' use such as convenience kits to aid in the implantation of the Rocket IPC.

7. INDICATIONS FOR USE

7.1 The Rocket IPC Insertion Kit and the 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.

The devices are indicated for:

1. The Palliation of dyspnea due to pleural effusion
2. Providing pleurodesis (resolution of 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.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

8.1 The Rocket IPC has the same intended use and the same technological characteristics as the identified predicate device.

8.1.1 The system employs the same technologies as the identified predicate including:

8.1.1.1 Fenestrated silicone catheter with a one-way silicone valve mechanism to prevent the reflux of fluid or air, a polyester cuff, and a radiopaque barium sulfate stripe.

8.1.1.2 Convenience kits are provided to aid in the insertion of the catheter, to aid in the removal of excessive pleural fluid, and to dress the wound site.

8.1.1.3 The catheter system uses the vacuum from a drainage bottle as a negative pressure to remove fluid from the pleural space quickly and efficiently

8.1.2 The system has the same technical characteristics including;

8.1.2.1 Materials: Biocompatible Silicone tubing, polyester cuff, and silicone adhesive are implanted in the pleural space

8.1.2.2 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*

9.1.2 ISO 10993-3: 2009 *Biological evaluation of medical devices – Part3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

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

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

9.1.5 ISO 10993-10: 2009 *Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity*

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

9.1.7 ISO 10993-12: 2009 *Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials*

9.1.8 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*

9.1.9 ISO11137-2:2007 *Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose*

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

9.1.11 USP <85> *Bacterial Endotoxins Test*

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

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

9.1.14 EN 868-5:1999 *Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods*

9.1.15 ISO15223-1 *Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements*

9.1.16 ISO 13485:2003 *Medical devices – Quality management systems – Requirements for regulatory purposes*

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

9.2 A list of Performance Testing conducted on the Pocket 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 shown in Table 7.1 below:

Table 7.1: 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 >4 mm)	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 >4 mm)	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	EN1617:1997 4.6 (including Annex B)	3	NPD QA 1052	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 through the catheter in millilitres per minute.	PASS

10 SUBSTANTIAL EQUIVALENCE

10.1 The technology characteristics of the Rocket Medical IPC system are slightly different in the following ways.

Although the premise of inserting a silicone catheter to drain pleural fluid and the technique of insertion are identical to the Pleurx version, the one way valve design itself is slightly different. However the performance and its intended use are identical.

The way the catheters are connected differs in that the Pleurx catheter has a push fit system, whereas the Rocket Medical system has a push fit and bayonet cap to ensure that dislocation does not occur.
With regards to the drainage bottles, only a 500ml version will be supplied as compared to the Pleurx 500ml and 1000ml bottles.

Also the ways that the vacuum is engaged and controlled are different.

Pleurx require you to pierce a foil lid to engage the vacuum whereas the Rocket system requests that a clip is removed. These differences do not change the function of the product; they are simply differing ways of engaging the vacuum.

To apply vacuum to the patient the Pleurx drainage bottles ask you to open a pinch clamp. If the patient wishes to stop draining at any time or for any reason the patient must close the pinch clamp to stop the application of vacuum.

The Rocket Medical version has an enclosed valve control with which the patient or clinician presses down on the button, this will apply the vacuum. If the patient wishes to stop draining at any time or for any reason the patient simply stops pressing the button and the system will stop the application of vacuum.

Verification and validation of the Rocket IPC System 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. Additionally, the test results demonstrated substantial equivalence of the Rocket IPC to its predicate device:

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 Pleural Catheter System (K112831), manufactured by CareFusion

10.1.2 Clinical Equivalence Justification

	Predicate device(s) in current use	Devices for evaluation	Gap Analysis
Description / code / reference	Pleurx Pleural Catheter Kit, 500ml/1000ml Drainage bottle	Rocket Medical IPC Insertion pack 500ml Drainage bottle	Identify reasons for and significance of differences
Essential dimensions	15.5Fg x 400mm Catheter, 500ml/1000ml	16Fg x 400mm Catheter, 500ml Drainage bottle.	
Material specifications	Silicone, valve material, bottle material	Silicone, valve material, bottle material	none
Operating environment	Body temperature, pleural space, subcutaneous tissue	Body temperature, pleural space, 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 catheters with a 3mm ID. As shown in the the testing documented.
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 pleural space 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 pleural space 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. As many in this patient group have thickend pleura 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 of vacuum. The patient can then titrate this level of vacuum to a personal level of comfort.
Method of sterilisation	EtO	EtO	none

T. Charlton

Tracy Charlton
Regulatory Affairs Manager

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

February 1, 2013

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

Re: K123033
Trade/Device Name: Rocket Indwelling Pleural Catheter (IPC) System
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: II
Product Code: DWM
Dated: January 2, 2013
Received: January 15, 2013

Dear Ms. 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.

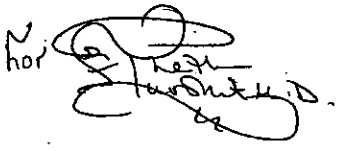
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123033

Device Name: Rocket Indwelling Pleural Catheter (IPC) System

Indications for Use:

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Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal Albert E. Moyal 2013.01.29 13:46:28 -05'00' for LS

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123033