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Revised 510(k) K123033 SUMMARY 10th January, 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
Address: 2-4 Sedling Road, Wear Industrial Estate, Washington, Tyne and Wear NE38 9BZ United Kingdom
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Fax: 00 44 191 416 5693

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:


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


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


9.1.11 USP <85> Bacterial Endotoxins Test

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


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

9.2 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>
<thead>
<tr>
<th>Test</th>
<th>Test Method or Standard</th>
<th>Sample Size</th>
<th>Final Report</th>
<th>Accept/Reject Criteria</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance to deformation</td>
<td>EN 1617:1997 4.2 (including Annex A)</td>
<td>3</td>
<td>NPD QA</td>
<td>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.</td>
<td>PASS</td>
</tr>
<tr>
<td>Force at break – connections</td>
<td>EN 1617:1997 4.3.1; EN 1618:1997 Annex F</td>
<td>3</td>
<td>NPD QA</td>
<td>The minimum force at break for connections shall be 15 N. (Nominal outside diameter &gt;4 mm)</td>
<td>PASS</td>
</tr>
<tr>
<td>Force at break – Drainage catheters and all other parts of the system</td>
<td>EN 1617:1997 4.3.2; EN 1618:1997 Annex B</td>
<td>3</td>
<td>NPD QA</td>
<td>The minimum force at break for catheter and all other parts of system shall be 20 N. (Nominal outside diameter &gt;4 mm)</td>
<td>PASS</td>
</tr>
<tr>
<td>Freedom from leakage – During aspiration or vacuum</td>
<td>EN 1617:1997 4.5; EN 1618:1997 Annex D</td>
<td>3</td>
<td>NPD QA</td>
<td>Neither the drainage system nor any components shall leak at the maximum negative pressure stated by the manufacturer</td>
<td>PASS</td>
</tr>
<tr>
<td>Impact resistance – Collection device</td>
<td>EN 1617:1997 4.6 (including Annex B)</td>
<td>3</td>
<td>NPD QA</td>
<td>The collection device shall not leak</td>
<td>PASS</td>
</tr>
<tr>
<td>Impact resistance – Suction Source</td>
<td>EN 1617:1 1987 4.6 (including Annex B)</td>
<td>3</td>
<td>NPD QA</td>
<td>The suction source shall not show any loss of vacuum greater than 2%</td>
<td>PASS</td>
</tr>
<tr>
<td>Flow Rate</td>
<td>EN 1618:1997 Annex D</td>
<td>3</td>
<td>NPD QA</td>
<td>Calculate the arithmetic average of three determinations and express it as water flow rate through the catheter in millilitres per minute.</td>
<td>PASS</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Description (Code/Reference)</th>
<th>Predicate device(s) in current use</th>
<th>Devices for evaluation</th>
<th>Gap Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS 500</td>
<td>Pleural Pleural Catheter Kit, 500ml/1000ml Drainage Bottle</td>
<td>Rocket Medical IPC Insertion pack, 500ml Drainage bottle</td>
<td>Identify reasons for and signiﬁcance of differences</td>
</tr>
<tr>
<td>Essential dimensions</td>
<td>15.5Fg x 400mm Catheter, 500ml/1000ml</td>
<td>16Fg x 400mm Catheter, 500ml Drainage bottle</td>
<td>none</td>
</tr>
<tr>
<td>Material specifications</td>
<td>Silicone, valve material, bottle material</td>
<td>Silicone, valve material, bottle material</td>
<td>none</td>
</tr>
<tr>
<td>Operating environment</td>
<td>Body temperature, pleural space, subcutaneous tissue</td>
<td>Body temperature, pleural space, subcutaneous tissue</td>
<td>Despite stated differences between the catheters, the catheters measure identically and are both 9mm OD catheters with a 3mm OD. As shown in the testing documented.</td>
</tr>
<tr>
<td>Design concept</td>
<td>15.5Fg x 400mm Catheter with one way valve</td>
<td>16Fg x 400mm Catheter with one way valve</td>
<td>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 thickened 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 adjust the level of vacuum to a personal level of comfort.</td>
</tr>
<tr>
<td>Principles of operation</td>
<td>Catheter is inserted using a mixture of wire guided and tunnelled technique. When instut 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.</td>
<td>Catheter is inserted using a mixture of wire guided and tunnelled technique. When instut 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.</td>
<td></td>
</tr>
<tr>
<td>Method of sterilisation</td>
<td>EO</td>
<td>EO</td>
<td>none</td>
</tr>
</tbody>
</table>

Tracy Charlton  
Regulatory Affairs Manager
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,

[Signature]

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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

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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 for LS

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