September 9, 2021

Rocket Medical Plc
Tracy Charlton
Regulatory Affairs Manager
2-4 Sedling Road
Washington, Tyne and Wear NE38 9BZ
UNITED KINGDOM

Re: K210509
Trade/Device Name: Rocket Platinum Cured Catheter
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: II
Product Code: DWM, PNG
Dated: August 6, 2021
Received: August 16, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B Bell, Ph.D.
Director
THT3A1: Renal, Gastrointestinal,
Obesity and Transplantation Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210509

Device Name
Rocket Platinum Cured Catheter

Indications for Use *(Describe)*
The Rocket IPC Platinum Cured Catheter is indicated for intermittent, long-term drainage of symptomatic, recurrent, effusion or ascites, including malignant effusion or ascites and other recurrent effusions or ascites 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.

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.

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SECTION 5: 510(K) SUMMARY

1. SUBMITTER

Name:	Rocket Medical Plc.
Address:	Sedling Road Washington, Tyne & 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:	February 15th, 2021

2. DEVICE

Trade Name:	Rocket Platinum Cured Catheter
Common Name:	Rocket Platinum Cured Catheter
Classification Name:	Patient Care Suction Apparatus Peritoneal dialysis system and accessories
Classification:	Class II, 21 CFR 870.5050 Class II, 21 CFR 876.5630
Product Code:	DWM PNG

3. PREDICATE DEVICE

3.1 The Rocket Platinum Cured Catheter is claimed to be substantially equivalent to the following
legally marketed predicate devices:

3.1.1 Rocket Indwelling Pleural Catheter (IPC) System (K123033) & Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit (K152105).

Verification and validation of the Rocket IPC Platinum Cured Catheter was performed through extensive bench testing, sterilization, packaging and shelf life testing. Results of the testing demonstrated that the Rocket IPC Catheter design met all specifications and is adequate for its intended use. Additionally, the test results demonstrated substantial equivalence of the Rocket IPC Catheter to its predicate device:

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

K123033 – Rocket Indwelling Pleural Catheter (IPC) System,

K152105 – Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit

4. DEVICE DESCRIPTION

4.1 The pleural space consists of two thin membranes, one lining the lung and the other lining the chest wall. Draining away the fluid can help relieve breathlessness for a short period, but the fluid often builds up again. While it is possible to have repeated drainage with a chest drain insertion, this could require repeated hospital visits. The IPC is a way of allowing fluid to be drained repeatedly without the painful drainage procedures and without having to come to hospital. The Rocket IPC Platinum Cured Catheter is a fenestrated silicone drainage catheter indicated for intermittent, long-term drainage of symptomatic, recurrent, effusion or ascites, including malignant effusion or ascites and other recurrent effusions or ascites that do not respond to medical management of underlying disease. 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 body. The Rocket platinum Cured Catheter is used alongside the Rocket IPC drainage line and Rocket IPC bottles (these we included in the Rocket Indwelling Pleural Catheter (IPC) System (K123033) & Rocket Indwelling Peritoneal Catheter (IPC) Insertion Kit (K152105).

4.2 The intended patient population is patients requiring external drainage of pleural effusions or abdominal ascites (patients suffering from fluid build-up with within the pleural/peritoneal space).

5. INDICATIONS FOR USE

5.1 The Rocket IPC Platinum Cured Catheter is indicated for intermittent, long-term drainage of symptomatic, recurrent, effusion or ascites, including malignant effusion or ascites and other recurrent effusions or ascites 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

6.1 The Rocket Platinum Cured Catheter has the same intended use and the same technological characteristics as the identified predicate device.

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

6.1.1.1 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.

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

6.1.2 The system has the same technical characteristics including;

6.1.2.1 Materials: Biocompatible Silicone tubing, polyester cuff, and silicone adhesive is implanted in the pleural / peritoneal space.

6.1.2.2 Sterility Assurance Level: $1x10^{-6}$.

7. PERFORMANCE DATA

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

7.1.1 ISO 10993-1:2009 - *Biological evaluation of medical devices Part 1: Evaluation and Testing*.

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

7.1.3 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.

7.1.4 ASTM F1980- 07(2011): Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices batch testing.

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

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

7.1.7 ISO 15223:2000 Medical Devices – *Symbols to be used with medical device labels, labeling, and information to be supplied.*

7.1.8 EU MDD Applicable sections of the European Medical Device Directive

(MDD) 93/42/EEC as amended by 2007/47/EC.

7.1.9 EU MDR Applicable Sections of the European Medical Device Regulation (MDR) 2017/745/EU amended 2020/561.

7.1.10 2016 FDA Biocompatibility Guidance - Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, June 16, 2016.

7.1.11 ISO 10993-1 (2018) *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.

7.1.12 ISO 10993-2 (2006) Biological Evaluation of Medical Devices – Part 2: Animal welfare requirements.

7.1.13 ISO 10993-3 (2014) Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.

7.1.14 ISO 10993-5 (2009) Biological Evaluation of Medical Devices – Part 5: Tests for *in vitro* cytotoxicity.

7.1.15 ISO 10993-6 (2016) Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation.

7.1.16 ISO 10993-10 (2010) Biological Evaluation of Medical Devices – Part10: Tests for irritation and skin sensitization.

7.1.17 ISO 10993-11 (2017) Biological Evaluation of Medical Devices– Part 11: Tests for systemic toxicity.

7.1.18 ISO 10993-12 (2012) Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.

7.1.19 ISO 10993-17 (2002) Biological Evaluation of Medical Devices – Part 17: Establishment of allowable limits for leachable substances.

7.1.20 ISO 10993-18 (2020) Biological Evaluation of Medical Devices – Part 18: Chemical characterization of materials.

7.1.21 ASTM Standard D4169 Standard Practice for Performance Testing of Shipping Containers and Systems

7.2 A list of Performance Testing conducted on the Rocket IPC Catheter includes:

7.2.1 Sterilization Validation

7.2.2 Biocompatibility Validation

7.2.3 Packaging Validation

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

7.3 A Summary of Standards Based compliance testing conducted on the Rocket IPC Catheter is shown in Table 9.1 and 9.2 below:

Table 9.1: Summary of Verification 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 - 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 (73.2-73.6 cmHg)	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

Table 9.2: Summary of Further Testing Performed

Ref No.	Test Performed	Results
A1 584464	MEM Elution GLP Report	PASS
A2 584476	ISO Guinea Pig Maximization Sensitization Test	Did not elicit a sensitization response
A3 584477	ISO Intracutaneous Reactivity Test	PASS
A4 584454	ISO Acute Systemic injection Test	PASS
A5 584455	Rabbit Pyrogen Test (Material Mediated) ISO	Requirements Met
A6 584456	Subacute 14-day Intra Peritoneal Toxicity Study in Mice	PASS
A7 584465	The Salmonella Typhimurium Reverse Mutation Assay	Non-Mutagenic
A8 584466	Chromosome Aberration Assay	PASS
A9 584462	In Vivo Mouse Micronucleus Assay	Non-Mutagenic
A10 584463	In Vitro Mouse Lymphoma Assay	Non-Mutagenic
A11 584453	Intramuscular Implant Test Thirteen Week Duration	Non-Irritant
A12 584452	Intramuscular Implant Test Six Month Duration	No-Irritant
19T 35058-11, 12, 13	Chemical Characterization	Refer to Test
267037	RA Final Evaluation of Local Tissue Effects of ZASEM222 Catheter Assembly following intramuscular Implantation in the Rabbit. **(ZASEM222 is now renamed as ZASEM297).**	Refer to Test
UK000326 – Rev 1	Biological Risk Assessment, ZASEM222 Platinum Cured Silicone Catheter including ZDLTR043 Steel Dilator).	Refer to Test
54400-16-MT Transport Study Report J15474-TX-1		Refer to Test
EtO Residual Test Reports IPC		Original Catheter in substantial equivalence 510k

8 CONCLUSIONS

K152033 - 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. 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: PleurX Pleural Catheter System (K112831), manufactured by CareFusion

K152105 - 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.