

K972867

**Rocket Medical plc - 510(k) Notification
Craft™ Suction Units**

OCT 24 1997

Summary of Safety and Effectiveness

**Craft™ Suction Pump
Craft™ Duo-Vac Suction Pump**

In the Code of Federal Regulations, relative to the medical devices reviewed by the General and Plastic Surgery devices classification panel, FDA identified Powered suction pumps as a Class II device (878.4780).

These devices, registered by Rocket Medical plc (Establishment number: 8010022/9610632) are substantially equivalent to devices which are currently in commerce and have been submitted to the FDA and found to be substantially equivalent. One such device is the Pioneer Pro-Pump (K# 914220) and the Pioneer Pro-Pump Dual Control (K# 914241), both found substantially equivalent 920304, produced by Pioneer Medical Inc., 34 Laurelcrest Road, Madison, CT 06443, USA.

The device is indicated for use to provide low flow regulated negative pressure for general suction and aspiration. These devices are safe and effective for the above application and have been tested to confirm their safety and effectiveness in this format for over 12 years, without incident in the UK.

The Craft™ Suction Pumps have been developed to provide a smooth low volume vacuum at variable negative pressure. The device has the same technological characteristics as the predicate device, vacuum being activated by a foot operated switch controlled by the surgeon. The range of vacuum being variable from 0-450mmHg and adjustable over this range by a pre-set control. Vacuum is provided by a quiet diaphragm pump, working from a mains voltage supply (USA 110V 60Hz). An overflow bottle provides a measure of safety to prevent aspirated fluids being drawn into the vacuum power unit. The trap also acting as a reservoir to provide an even vacuum pressure during procedures. The foot control has an air-operated solenoid, switching the main pump unit. No electrical connections are made to the sealed foot operated control.

Rocket Medical plc continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION

I hereby certify that this Summary of Safety and Effectiveness applies for the above indicated devices.



Signed by Leslie Todd
Quality Assurance and Regulatory Affairs Manager
Rocket Medical plc
Wear Industrial Estate,
Washington
Tyne & Wear,
England. NE37 1NE
Tel: 011 44 191 416 6776

21st October 1997



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. L. Todd
Quality Assurance & Regulatory Affairs Manager
Rocket Medical PLC
Wear Industries Estate
Washington Tyne & Wear
NE37 1NE
United Kingdom

OCT 24 1997

Re: K972867
Trade Name: Craft Duo-Vac Suction Unit, Craft Suction
Unit
Regulatory Class: II
Product Code: ICX
Dated: July 11, 1997
Received: August 4, 1997

Dear Mr. Todd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

Page 2 - Mr. Todd

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Rocket Medical plc - 510(k) Notification
Craft™ Suction Units

Page 1 of 1

Device Name: Craft™ Suction Pump and Craft™ Duo-Vac Suction Pumps

Indications for Use:

A vacuum powered body fluid suction apparatus could be used in a variety of clinical conditions, however, these particular units have been developed to:

Provide Low flow regulated negative pressure for general suction and aspiration.



Signed L. Todd

QA and Regulatory Affairs Manager

Rocket Medical Plc

11th July 1997

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

Concurrence of CDHR, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K972847

Prescription use

OR

Over-The -Counter Use

(Optional Format 1-2-96)