2 510(k) Summary

Submitter:	Orqis Medical Corporation 14 Orchard Road, Suite 100 Lake Forest, CA 92630
Contact Person::	Ryan Kelly Senior Regulatory Affairs Specialist
Date Prepared:	December 21, 2007
Trade Name:	Orqis Extracorporeal Blood Pumping System Orqis Blood Pump Orqis Motor Orqis Controller Orqis Flow Sensor Orqis Pump Tubing
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-roller type (21 CFR 870.4360) Control, Pump Speed, Cardiopulmonary Bypass (21 CFR 870.4380) Tubing, Pump, Cardiopulmonary Bypass (21 CFR 870.4390)
Predicate Devices:	Levitronix CentriMag® Extracorporeal Blood Pumping System, K020271 Cardiac Assist TandemHeart Escort Controller, K061369 Olsen Medical Sales Plastron Pump Tubing, K013578
Device Description:	The Orqis Extracorporeal Blood Pumping System consists of a pump, independent motor unit, a controller, a flow sensor, and some pump tubing. The system also has two accessories: a holster for the pump and motor, and a controller stand. The Orqis Blood Pump is a sterile, single-use, disposable, non-pulsatile, non-roller pump that utilizes a rotor to impart energy to the blood in an extracorporeal circuit through centrifugal forces. The inlet of the pump runs concentric with the axis of the rotor.

	The Orqis Motor is a small, compact, reusable unit that holds the disposable blood pump and drives the rotor inside the blood pump. The Motor turns a magnet that is hermetically sealed in the pump's rotor at a speed that is set by the controller. The outer shell of the motor is built from aluminum and polycarbonate. The motor is provided non-sterile. The Orqis Controller is a microprocessor-based device, which drives and controls the blood pump, through the motor. The Controller also provides monitoring of motor speed, fluid flow, and pressure through the use of alphanumeric display and audible and visual alarms. The Orqis Flow Sensor is an ultrasonic flow meter that measures fluid flow through standard 3/8" tubing. The Orqis Pump Tubing is medical grade PVC tubing used to connect the Blood Pump to external devices. The Pump Tubing is provided sterile.
Intended Use:	The Orqis Extracorporeal Blood Pumping System is intended to be used as a blood pumping unit in extracorporeal circulation for cardiac support that may, or may not, require cardiopulmonary bypass (for up to six hours). The Orqis Pump Tubing is intended for use in extracorporeal circuits designed for cardiac support.
Comparative Analysis:	The Orqis Extracorporeal Blood Pumping System has been demonstrated to be as safe and effective as the predicate device for its intended use.
Functional Testing:	The Orqis Extracorporeal Blood Pumping System has successfully undergone functional testing demonstrating equivalence to the predicate device
Conclusion:	The Orqis Extracorporeal Blood Pumping System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Mr. Ryan Kelly
Senior Regulatory Affairs Specialist
Orqis Medical Corporation
14 Orchard Road, Suite 100
Lake Forest, CA 92630

Re: K073631
Orqis® Extracorporeal Blood Pumping System
Regulation Number: 21 CFR 870.4360
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-roller type
Regulatory Class: Class III
Product Code: KFM
Dated: June 11, 2008
Received: June 13, 2008

Dear Mr. Kelly:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Statement

510(k) Number (if known): K073631

Device Name: Orqis® Extracorporeal Blood Pumping System

Indications for Use:

The Orqis Extracorporeal Blood Pumping system is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants, etc).

The Orqis Pump Tubing is indicated for use in extracorporeal circuits for circulatory support lasting six-hours or less.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vredevoe

(Division Sign-Off)
Division of Cardiovascular Devices

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