510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. Submitter's Name / Contact Person

Manufacturer
Waters Medical Systems
2112 Fifteenth Street NW, Suite A
Rochester MN 55903-6117

Contact Person
Dave Schollman
General Manager
Tel: (800)426-9877; Fax: (507)252-3700

2. General Information

Trade Name	RM3 Renal Preservation System
Common / Usual Name	Renal preservation system
Classification Name	Isolated kidney perfusion and transport system and accessories
Identification of Equivalent Devices	Waters Medical Systems – RM3 Renal Preservation System

3. Intended Use

The RM3 Renal Preservation System is intended to be used to maintain kidneys for transplant.

4. Device Description

The RM3 Renal Preservation System is a lightweight, transportable and self-contained renal preservation system, designed to support static monitoring and transportation of kidneys. The RM3 system provides controlled kidney perfusion of hypothermic physiologic solutions, and monitors, displays, trends, and saves important perfusion parameters, including: perfusate flow, temperature, pressure, and renal resistance. The RM3 system control unit can be configured to signal an audio and visual alarm for user-selected limits, and print user-selected data and waveforms.

The RM3 Renal Preservation System is a two-part system comprising a control unit for perfusion and monitoring of one or two kidneys, and a sterile, disposable single-use cassette used to contain and circulate perfusate to the kidneys.

5. Substantial Equivalence Comparison

The proposed RM3 Renal Preservation System and the predicate RM3 Renal Preservation System are identical in intended use and methodology. The two systems are substantially similar in system components; they share an identical control unit and both utilize a sterile, single-use, disposable cassette. The cassette module for both the subject and predicate devices are substantially similar in design, configuration and materials. A minor material change in the cassette will improve manufacturability. The material change has been evaluated through risk analysis and a biomaterial safety assessment following established Design Control procedures. The disposable cassette module material changes raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2006

Mr. Dave Schollman
General Manager
Waters Medical Systems™
13705 26th Avenue North, Suite 102
MINNEAPOLIS MN 55441-3644

Re: K053169
Trade/Device Name: RM3 Renal Preservation System
Regulation Number: 21 CFR §876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Codes: KDK and KDN
Dated: December 21, 2005
Received: December 27, 2005

Dear Mr. Schollman:

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 (Premarket 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K053169

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053169

Device Name: **RM3 Renal Preservation System**

Indications for Use:

The RM3 Renal Preservation System is intended to be used to maintain kidneys for transplant.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053169

(Posted November 13, 2003)