DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1997

Mr. Dave Schollman
General Manager
Waters Instruments, Inc.
2411 Seventh Street, N.W.
P.O. Box 6117
Rochester, Minnesota 55903-6117

Re: K971571
RM3 Renal Preservation System—control unit
Dated: April 28, 1997
Received: April 30, 1997
Regulatory class: II
21 CFR §876.5880/Product code: 78 KDN

Dear Mr. Schollman:

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 (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 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: 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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K971571

-- 510[k] SUMMARY --

JUL 29 1997

1. Submitter Information

Waters Medical Systems,
a division of Waters Instruments Inc.
2411 Seventh Street N.W.
Rochester, MN 55903-6117

Contact: Dave Schollman, General Manager

Phone: 800-426-9877 tel
507-252-3700 fax

Estab't. Registration Number: 2123774

Summary Preparation Date: April 28, 1997

2. Device Names

Proprietary Name:	RM3 Renal Preservation System--contol unit
Common/Usual Name:	renal preservation system--control unit
Classification Name:	Isolated kidney perfusion and transport system and accessories (21 CFR 876.5880)
Classification:	Class II, Gastroenterology/Urology Panel

3. Predicate devices

MOX-100 Renal Preservation System TM2 Transport Module, a pre-amendment device.

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 control unit provides controlled kidney perfusion of hypothermic physiologic solutions, and monitors, displays, trends, and saves important perfusion parameters, including: perfusate flow temperature, rate and 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.

5. Intended use

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

6. Comparison of technological characteristics

The RM3 and the MOX-100 TM2 control units are identical in intended use and methodology. Both systems utilize pulsatile hypothermic perfusion to maintain kidneys for transplant. They are substantially similar in the means by which the pulsatile flow through the kidneys is accomplished, and both allow the user to maintain and monitor nearly the same important perfusion parameters within similar operating ranges. The control units are different in the RM3 automatically monitors, displays, and trends the perfusate pump rate, systolic, mean and diastolic pressures, perfusate temperature, and real-time arterial flow through each kidney, and calculates the renal resistance of each kidney. In the MOX-100 TM2 units the system operator must visually monitor these parameters by reading analog meters and must manually trend the data and calculate renal resistance. Additionally, control of perfusion pump power and rate and coolant circulation pump power different. Test results demonstrate that the RM3 control unit performance meets or exceeds the MOX-100 performance for each of the technologically different features.

April 28, 1997

ATTACHMENT 1: INTENDED USE STATEMENT

The Waters Medical Systems (Waters Instruments, Inc.) RM3 Renal Preservation System is intended to be used to maintain kidneys for transplant.

Robert R Ratliff
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971571

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____

April 28, 1997