K983076
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NOV 25 1998

Section I

510(k) Summary
Required by 21 CFR §807.92

I. Submitter:

A. Name: McKenna & Cuneo, L.L.P.

B. Address: 1900 K Street, NW
Washington, DC 20006

C. Phone and Fax Numbers: Phone: 202-496-7500
Fax 202-496-7756

D. Contact Person: Mr. Larry Pilot

II. Date of preparation of this Summary: August 13, 1998

III. Trade Name: Medisystems Transducer Protectors

IV. Common Name: Transducer Protectors

V. Classification Name: Hemodialysis System and Accessories

VI. The Marketed Device(s) to which Equivalence is Claimed: The Transducer Protectors that are the subject of this submission are substantially equivalent to those described in Medisystems 510(k) number K895856 for the design and construction of the device and to those described in the Trimed 510(k) number K820459B for the claim of viral retention.

VII. Product Description: Medisystems Transducer Protectors are designed to be used as protective devices for pressure monitors as well as to help maintain the sterility of the blood tubing fluid pathway. The 0.2 μm hydrophobic filter helps prevent cross-contamination by viruses, bacteria and particulate matter while preventing the flow of fluids to the hemodialysis machine pressure monitor.

VIII. Statement of Intended Use Compared to Predicate Device: Medisystems Transducer Protectors are single use, disposable prescription devices intended for use as protective devices for pressure monitors and to help protect the sterility of the fluid pathway. This is identical to the intended use of the legally marketed predicate device.

IX. Discussion of Technological Characteristics: The technical characteristics of the device consist of a filter housing that contains a 0.2 μm hydrophobic filter. The combination of the pore

size and hydrophobic nature of the filter also prevents the flow of fluids, viruses, bacteria, and particulate matter into the pressure monitor at pressures lower than the rated pressure of the device.

X. Safety and Effectiveness: To assure that the device is safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to; sterility, pyrogenicity, physical testing, and visual examination of both in-process and finished product.

The required testing is defined by written and approved procedures that conform to the product design specifications. This testing for the Medisystems Transducer Protectors is defined in detail in the "Device Master Records."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Medisystems Corp.
c/o Mr. Larry R. Pilot
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Re: K983076
Medisystem's In Line Transducer Protector
Dated: September 2, 1998
Received: September 2, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 FIB

Dear Mr. Pilot:

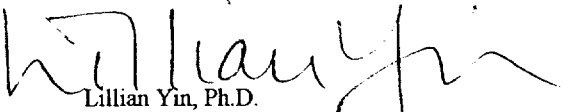
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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/dsma/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

Section A

510(k) Number (if known): _____

Device Name: Transducer Protectors

Indications For Use:

Medisystems Transducer Protectors are indicated for use as protective devices for pressure monitors on hemodialysis machines as well as to help protect the sterility of the blood tubing fluid pathway. The filter helps prevent cross-contamination by viruses, bacteria, and other particulate matter while preventing the flow of fluids to the hemodialysis machine's pressure transducer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use ✓ 510(k) Number K983076 Over-The-Counter Use _____

(Optional Format 1-2-96)