

AUG 18 1997

K971860
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Section I

**510(k) Summary
Required by 21 CFR §807.92**

I. Submitter:

A. Name: McKenna & Cuneo, L.L.P.
on behalf of Medisystems Corporation

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 R. Pilot

II. Date of preparation of this Summary: May 2, 1997

III. Trade Name: Medisystems Dialysis Priming Sets

IV. Common Name: Dialysis Priming Sets

V. Classification Name: Hemodialysis Accessories

VI. The Marketed Device(s) to which Equivalence is Claimed: The Dialysis Priming Sets which are the subject of this submission are substantially equivalent to those described in Medisystems' 510(k) number K811837 and in Japan Medical Co., LTD. 510(k) number K895882.

VII. Product Description: The Medisystems Dialysis Priming Sets provide a means of delivering fluids and medicaments from a collapsible container or vented bottle into a patient's vascular system during dialysis procedures. The set consists of a flexible drip chamber with a spike for attachment to the solution container, an adjustable clamp that regulates flow, a flexible delivery tube with a two port connector. This connector will allow connection of the set to devices with compatible female luer connectors. The set will also allow connection of a separate device with compatible male luer to the set's female luer connector.

VIII. Statement of Intended Use Compared to Currently Marketed Predicate Device: The intended use of the Medisystems Dialysis Priming Sets is to provide a means to deliver fluids and medicaments from a collapsible container or vented bottle into a patient's vascular system during dialysis procedures. This intended use is identical to that of the currently marketed predicate devices.

IX. Discussion of Technological Characteristics: The technical characteristics of the device may be divided into three elements:

1. A spike connector that allows access to containers of solution.
2. Tubing, drip chamber, and adjustable clamp which allow the solution to be delivered at a controlled rate.
3. A means of connection of the set to other devices such as an extracorporeal tubing set or an I.V. needle set in order to deliver the solution into the vascular system.

These technological characteristics are identical to those of the currently marketed predicate device.

Some of the materials of construction of the proposed device differ from those of the currently marketed predicate device. This difference has no effect upon the safety and effectiveness of the device as demonstrated by the results of biocompatibility testing and performance testing of the proposed 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 Dialysis Priming Sets is defined in detail in the "Device Master Records."

Modifications of the currently marketed device which include additional labeling and a change in some of the materials of construction will have no effect upon the safety or effectiveness of the device. The additional labeling provides alternate directions for use of the device during hemodialysis procedures for priming and rinse-back. The change in some of the materials of construction have been shown to have no effect upon safety and effectiveness by the results of biocompatibility and performance testing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1997

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

Re: K971860
Medisystems Dialysis Priming Set
Dated: May 20, 1997
Received: May 20, 1997
Regulatory Class: II
21 CFR §876.5820/Product Code: 78 KOC

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 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

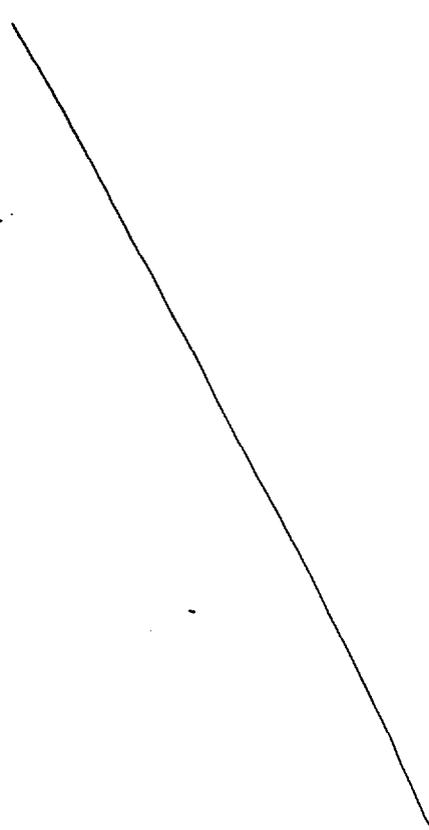
Section A

510(k) Number (if known): K971860

Device Name: Medisystems Dialysis Priming Sets

Indications For Use:

The proposed Dialysis Priming Sets are indicated for use to provide a means to deliver fluids and medicaments from a collapsible container or vented bottle into a patient's vascular system during dialysis procedures.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Drew R. Sattling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971860

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use