

K963668

Section I

AUG 15 1997

**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: August 7, 1996

III. Trade Name: Medisystems Peritoneal Dialysis Sets

IV. Common Name: Peritoneal Dialysis Sets

V. Classification Name: Peritoneal Dialysis System and Accessories

VI. The Marketed Device(s) to which Equivalence is Claimed: The Peritoneal Dialysis Sets which are the subject of this submission are substantially equivalent to those manufactured by Fresenius USA.

VII. Product Description: The Medisystems' Peritoneal Dialysis Sets comprise a number of codes to facilitate peritoneal dialysis procedures. The Medisystems' Peritoneal Dialysis Sets consist of tubing and componentry to allow connection between a container of dialysate solution and the patient's indwelling catheter for instillation into and retention of the dialysate in the peritoneal cavity. The Peritoneal Dialysis Sets then allow exchange of fresh dialysate by providing a means to aseptically drain the used dialysate from the peritoneal cavity into a collection bag for disposal.

VIII. Statement of Intended Use Compared to Predicate Device: The intended use of the Medisystems' Peritoneal Dialysis Sets is identical to that of the predicate device; to provide a means to exchange dialysate solution in peritoneal dialysis procedures for the treatment of patients with kidney failure.

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

1. Components that allow access to bags of dialysis solution and to the patient's in-dwelling catheter.
2. Tubing components which allow the dialysis solution to be instilled into or drained from the peritoneal cavity.
3. A drain bag that allows aseptic collection of the used dialysis solution drained from the patient.

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

Multiple codes of the product are offered to accommodate different physicians' prescriptions and patient needs. These codes include various means of connection to a dialysis solution container, connection to the patient's in-dwelling catheter, and alternate materials of construction.

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 Peritoneal Dialysis Sets is defined in detail in the "Device Master Records."



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Medisystems Corporation
c/o Ms. Suzan Onel
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Re: K963668
Medisystems Peritoneal Dialysis Sets
Dated: May 19, 1997
Received: May 19, 1997
Regulatory class: II
21 CFR §876.5630/Product code: 78 KDJ

Dear Ms. Onel:

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

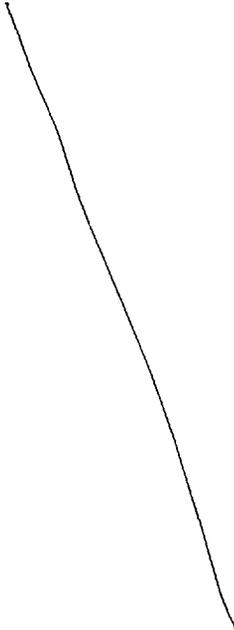
Enclosure

510(k) Number (if known): K963668

Device Name: Peritoneal Dialysis Sets

Indications For Use:

Medisystems Peritoneal Dialysis Set product line is indicated for use in compatible peritoneal dialysis procedures. Specific codes are indicated respectively for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Cycler Peritoneal Dialysis.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use

Robert R. Nathan
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K963668

(Optional Format 1-2-96)