K990803

Page 1 of 2

JAN - 6 2000

Section I

510(k) Summary
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: February 25, 1999

III. Trade Name: Medisystems Buttonhole Needle Sets

IV. Common Name: Access Device

V. Classification Name: Single Lumen Hypodermic Needle

VI. The Marketed Device(s) to which Equivalence is Claimed: The Medisystems Buttonhole Needle Sets that are the subject of this submission are substantially equivalent to Needle Sets described by Medisystems' 510(k) number K823068 for Medisystems Arterial Venous Fistula Needles in terms of their design and materials of construction and Becton-Dickinson's 510(k) number K951254 for Hypodermic Needles in terms of their indications for use.

VII. Product Description: The Medisystems Buttonhole Needle Set consists of a hollow, rigid needle/cannula, a flexible tube, and locking connector to provide access through the skin at a constant or "buttonhole" site. Different degrees of point sharpness are offered to accommodate creation of the buttonhole site and cannulation through an established buttonhole site.

VIII. Statement of Intended Use Compared to Predicate Device: The indications for use of the Arterial Venous Fistula Needles predicate device are to allow access during dialysis procedures. Medisystems Buttonhole Needle Sets are indicated for use as an access device to percutaneously inject fluids into, or withdraw fluids from, the body using a constant site or "buttonhole" method of needle insertion. This is identical to the indications for use of the hypodermic needle predicate

device except for the constant site of use for the Medisystems Buttonhole Needle Sets. Both predicate devices are used typically at a different site for each cannulation or puncture.

IX. Discussion of Technological Characteristics: The technical characteristics of the Medisystems Buttonhole Set consist of a rigid needle cannula mounted on a hub with wings or finger grips to allow insertion through the skin. The needle hub is bonded to a flexible tube and locking connectors that allow attachment to other compatible medical devices.

Different degrees of needle sharpness are offered. The sharp version of the Medisystems Buttonhole Needle Set is used to allow the initial creation of a scar tunnel or buttonhole. The duller versions are used for repeated access through the buttonhole site. The duller point and cutting surfaces of the needle/cannula minimize cuts in the adjacent tissue, enlargement of the hole, and bleeding along the needle's path.

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 Buttonhole Needle Sets 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

JAN - 6 2000

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

Re: K990803
Medisystems Buttonhole Needle Sets
Dated: November 1, 1999
Received: November 1, 1999
Regulatory Class: II
21 CFR §876.5540/Procode: 78 FIE

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K990803

Device Name: Buttonhole Needle Sets

Indications For Use:

Medisystems Buttonhole Needle Sets are indicated for use as an access device for dialysis and pheresis procedures using a constant site or "buttonhole" method of needle insertion.

(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 _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990803/S002