K984600

JUN 3 1999

Inlet Medical Inc.
Metra Positioning System (PS) Procedure Kit

1. Name and Address

Inlet Medical Inc.
10180 Viking Drive
Eden Prairie, MN 55344
Telephone (612) 942-5034
Facsimile: (612)-829-7112

Contact Person – Bob Gabler

Date of summary preparation – May 19, 1999

2. Device Name

Proprietary Name:	Metra Positioning System (PS) Procedure Kit
Common/Usual Name:	Metra PS Procedure Kit
Classification Name:	Manual Surgical Instrument for General Use

3. Identification of the predicate or legally marketed device(s) to which equivalence is being claimed

The Inlet Medical Metra PS Procedure Kit is substantially equivalent to the Inlet Medical Needle Point Suture Passer Instrument Set (K980123).

4. Device Description

The components of the Metra PS Procedure Kit are One needle point suture passer, one grasper, one knot pusher/ positioning device, suture material, and two suture guides.

5. Intended Use

This procedure kit is intended to facilitate passage of suture through the soft tissues of the body during laparoscopic surgery. It is to be used only by surgeons trained in laparoscopic surgery.

6. **A statement of how the technological characteristics of the device compare to those of the predicate of legally marketed device(s) cited.**

The Inlet Medical Inc. disposable Metra PS Procedure Kit is substantially equivalent to the Needle-Point Suture Passer Instruments Set. Both the Metra PS Procedure Kit and the predicate device, Needle Point Suture Passer Instrument Set (K980123), are similar in design. The predicate device consists of a Needle Point Suture Passer and 2 suture guides. They both are used to facilitate passage of suture through the soft tissues of the body during laparoscopic surgery. The knot pusher/positioning instrument and the suture material (P840041) are being packaged in the Metra PS Procedure Kit for convenience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Mr. Mark Sterrett
MedVenture Regulatory Affairs Specialist
MedVenture Technology Corporation
2400 Crittenden Drive
Louisville, KY 40217

Re: K984600/S1
Metra Positioning System (PS) Procedure Kit
Dated: April 7, 1999
Received: April 9, 1999
Regulatory Class: Class II
21 CFR 876.1500/Product Code: 78 GCJ

Dear Mr. Sterrett:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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

510(k) Number (if known): K984600

Device Name: Metra Positioning System (PS) Procedure Kit

Indication For Use:

This procedure kit is intended to facilitate passage of suture through the soft tissues of the body during laparoscopic surgery. It is to be used only by surgeons trained in laparoscopic surgery.

(PLEASE DO NOT WRITE BELOW THIS LNE - CONTINUE ON ANOTHER PAGE IF NECESSAY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984600

(Optional Format 1-2-96)