K040036

MAR 18 2004

510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information

Inviro Medical
885 West Georgia Street
Suite 1200
Vancouver, BC V6C3E8
Canada

Phone Number: 604-688-6115

Fax Number: 604-451-7002

Contact: F. Ross Sharp, MD
President

Date: January 7, 2004

B. Device Information

Trade/Proprietary Name: Inviro Snap Safety 1 cc Insulin Syringe

Common name of device: Piston Syringe with Safety Feature

Classification Name: Piston Syringe with Safety Syringe

C: Predicate Device: B-D 1 cc Insulin Syringe
Inviro 6 cc Syringe

Predicate 510(k) #: K024112
K941450

D. Device Description:

The Inviro Snap Safety Insulin Syringe is a 1 cc retractable type anti-needlestick syringe. The syringe has a 100 unit scale in 1 unit increments. The Inviro Snap Safety Insulin Syringe is sterilized by gamma irradiation and supplied sterile in blister pack. One hundred blister packs are packaged in a chipboard box. Each Blister pack and chipboard box is labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.

After use, with the plunger fully compressed, a 180 degree rotation of the plunger couples the Adapter/Needle to the end of the plunger. After this coupling occurs withdrawal of the plunger causes the Adapter and the attached needle to be withdrawn into the safety of the barrel. In this position against the flange, lateral pressure on the plunger results in a controlled fracture of the plunger. Both the syringe and plunger are discarded in a Sharps container.

E. Intended Use:

The Inviro Snap Safety Syringes are intended for the subcutaneous injection of insulins. In addition, the Inviro Snap Safety Insulin Syringe is designed to aid in the prevention of needle stick injuries.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Inviro Snap Safety Insulin Syringe and the cited predicate devices.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

Prior to testing, First Article Inspections were conducted on all components. In addition, material verification was performed on all components.

The Inviro Snap Safety Syringe assembly was tested per the requirements of the ISO-FDA Modified Matrix, FDA/ODE General Program Memorandum - # G95-1 and ANSI/AAMI/ISO 10993-1:1997 for a External communicating device, Blood path, indirect for a period less than 30 days.

Biocompatibility testing included Cytotoxicity, Intracutaneous Reactivity, Maximization Sensitization Study, In Vitro Hemolysis Study, USP and ISO Systemic Toxicity Studies and USP Prorogen Study. The Inviro Snap Safety Syringe met all of the biocompatibility requirements.

The following performance tests were conducted to qualify the interface between the various components:

1. Force to assemble/disassemble cap
2. Force to separate Adapter from Cannula
3. Force to Snap off Plunger
4. Cannula Bending Test
5. Force required to press out Adapter from Barrel

The following tests were conducted to qualify the syringe assembly:

1. Freedom from air and liquid leakage past seals
2. Pressure Leakage Test
3. Plunger Action Force
4. Accuracy

The Inviro Medical Snap Safety 1 cc Insulin Syringe met all requirements.

The intended use of the Inviro Snap Safety Insulin Syringe is identical to that of the B-D 1 cc Insulin Syringe. Any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

Conclusion:

> The Inviro Snap Safety Insulin Syringe is substantially equivalent to the B-D 1 cc Insulin Syringe in indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2004

Inviro Medical
C/O Mr. James Barley
Regulatory Affairs
JB & Associates
885 West Georgia Street Suite 1200
Vancouver, BC V6C3E8
CANADA

Re: K040036
Trade/Device Name: Inviro Snap Insulin Safety Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: January 7, 2004
Received: January 9, 2004

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

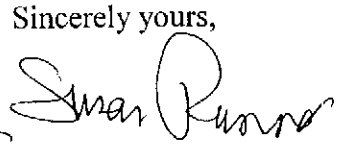
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040036

Indications for Use Statement

510(k) Number (if known): K040036

Device Name: INVIRO SNAP INSULIN SAFETY SYRINGE, 1 cc (100 units)

Indications for Use:

The Inviro Snap Safety Insulin Syringes are intended for the subcutaneous injection of insulins. In addition, the Inviro Snap Safety Syringe is designed to aid in the prevention of needle stick injuries.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040036

(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 ✓
(Per 21 CFR 801.109)