SEP 2 4 2003

K032780

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: August 25, 2003

B. Device Information

Trade/Proprietary Name:	Inviro Snap Safety Syringe
Common name of device:	Piston Syringe with Safety Feature
Classification Name:	Piston Syringe with Safety Syringe

C. Predicate Device: Inviro 6 cc Syringe

Predicate 510(k) #: K941450

D. Device Description:

The Inviro Snap Safety Syringe is a retractable type anti-needlestick syringe. The Inviro Snap Safety 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 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 After this coupling occurs withdrawal of the plunger causes the Adapter and the attached needle to be withdrawn into the safety of the barrel.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 Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the Inviro Snap Safety 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 Syringe and the cited predicate device.

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.

Tests were conducted to determine the accuracy of the scale on the Inviro Snap Safety Syringe. These tests consisted of weighing the syringe, filling the syringe to various increments, weighing the syringe, expelling the fluid and weighing the syringe once again. All weights were recorded. The mean and standard deviation was calculated for all increments. The scale met all accuracy requirements.

Verification Testing consisted of component and interface testing and finished assembly testing. The following tests were performed to verify the compatibility between the interfacing safety syringe components:

1. Force to assemble/disassemble cap – In this test, the average force along with the standard deviation is determined to assemble and disassemble the Cap from the Barrel. A good seal between the cap and barrel will reduce the chance that the cap will fall off and expose the needle.
2. Force to separate Adapter from Cannula – This test was conducted per ISO 7864:1993(E) paragraph 13.1. The average force along with the standard deviation was determined for separating the cannula from the adapter. The ISO Standard requires a minimum of 4.9 lbs of force to separate the cannula from the adaptor.
3. Force to Snap off Plunger – A torque gauge is used to snap off the plunger from the syringe. This test will verify that the plunger is not too difficult to snap off.
4. Cannula Bending Test – To verify the cannula can withstand the forces required to penetrate a medicine bottle septum.
5. Force required to press out Adapter from Barrel – This test determines the force required to push/press out the adaptor from the barrel. This test will assure that the adaptor is not pushed out during an injection.

To verify that the assembled devices met the design requirements, the following tests were performed:

1. Freedom from air and liquid leakage past seals – Medication leakage can occur around the plunger seal or around the needle holder. This test involves blocking the needle lumen and forcing the plunger handle forward. Pressure is increased incrementally and held for several seconds at each increment. The pressure at which leakage occurs and the location of the leak is recorded.
2. Pressure Leakage Test – This test was conducted per ISO 7886-1:1993(E) Annex D. In this test series, the system was submerged in liquid and an internal pressure of 43.5 and 400 PSI was applied. Any leakage past the seals was recorded.
3. Plunger Action Force – This test was conducted per ISO 7886-1:1993(E) Annex G. This test measures the force to initiate plunger action as well as the maximum and minimum forces required to move the plunger within the Barrel.

The intended use of the Inviro Snap Safety Syringe is identical to that of the cited predicate device. Verification testing showed that any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

Conclusion:

The Inviro Snap Safety Syringe is substantially equivalent to the Inviro 6 cc 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

SEP 2 4 2003

Inviro Medical
C/O Mr. James Barley
Regulatory Affairs
JB & Associates
28481 LA Falda
Laguna Niguel, California 92677

Re: K032780
Trade/Device Name: Inviro Snap Safety Syringe, 1cc, 3cc, 5cc, and 10cc,
Regulation Number: 880.5860
Regulation Name: Piston Syringe with Safety Feature
Regulatory Class: II
Product Code: MEG
Dated: September 3, 2003
Received: September 8, 2003

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: INVIRO SNAP SAFETY SYRINGE, 1 cc/ml

Indications for Use:

The Inviro Snap Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. 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: K032780

(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)