K092430

SEP - 4 2009

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

A. Submitter Information

Inviro Medical, Inc.
1755 North Brown Road
Suite 150
Lawrenceville, GA 30043

Phone Number: 678-405-4037
Fax Number: 678-405-4044

Establishment Number: 3005147037

Trade Name: InviroSnap Safety Syringe

B. Device Information

Trade/Proprietary Name:	InviroSnap Safety Syringe
Common name of device:	Safety Syringe
Classification Name:	Piston Syringe with Safety Syringe
Product Code:	80 MEG
Regulatory Class:	II
Classification Number:	880.5860
Reason for 510(k):	Special 510(k)

C. Predicate Device: InviroSnap 1, 3, 5 and 10 ml Safety Syringe

Predicate 510(k) #:	K032780
Predicate product code:	MEG

D. Device Description

The Inviro Medical InviroSnap Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. The InviroSnap Safety Syringe is designed to aid in the prevention of needle stick injuries.

The retractable type piston syringe is a plastic disposable anti-needlestick syringe made of the following components:

1 Barrel – The barrel has a scale showing the capacity of the syringe. In addition, the tip of the barrel has a luer lock fitting for the user to attach a needle.

2 Plunger – Once the plunger is fully depressed, it engages the needle assembly. As the plunger is retracted, the needle assembly is retracted into the barrel. Once the plunger is fully retracted and locked in place, the plunger is snapped off leaving the needle in the barrel of the syringe.

3 O-Ring – The O-ring minimizes the risk of leakage around the Adapter.

4 Stopper – The Stopper maintains the fluid in the barrel between the Adapter and Plunger.

5 Luer Assembly – The Luer Assembly facilitates passage of the fluid between the cannula and the barrel. In addition, the Luer Assembly holds the needle and engages the plunger after the injection.

6 Cannula – The cannula/needle penetrates the patient's skin to inject/withdraw fluid from the body.

7. Locking Ring – A plastic insert at the top of the barrel. After the injection, the health care professional retracts the plunger with the needle into the barrel. Once the plunger is fully retracted, the plunger is locked into position at the top of the barrel. This safety mechanism makes sure the needle can not be pushed back out the tip of the barrel.

8 Cap – Covers the cannula/needle until the syringe is to be used.

D. Device Description

After use, the health care professional fully depresses the plunger to engage the Luer Assembly. Once the Luer Assembly is engaged, pulling back 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.

The InviroSnap Safety Syringes are sterilized by Ethylene Oxide Gas 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.

E. Statement of Indications for Use

The InviroSnap 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 InviroSnap 1, 3, 5, 10 and 20 ml Safety Syringe and the cited predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The intended use of the InviroSnap 1, 3, 5, 10 and 20 ml Safety Syringes is identical to that of the cited predicate device. Any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

Performance testing consisted of compliance to the applicable sections of the following voluntary standards:

1. ISO 594-1:1986, "Syringe, Syringe Needle and Other Medical Apparatus 6% (Lu-Er) Taper Connector – Part One: General Requirement"
2. ISO 594-2:1986, "Syringe, Syringe Needle and Other Medical Apparatus 6% (Lu-Er) Taper Connector – Part Two: Locked Connector"
3. ISO 7886-1:1993, Sterile hypodermic syringes for single use
4. ISO 7886-4:2006, Sterile hypodermic syringes for single use, Syringes with re-use prevention feature
5. ISO 11135:2007; Medical Devices – Validation and Routine Control of EO Sterilization,

Conclusion:

The InviroSnap 1, 3, 5, 10 and 20 ml Safety Syringes are substantially equivalent to the InviroSnap 1, 3, 5 and 10 ml Safety Syringe in indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP - 4 2009

Mr. James Barley
Director of Regulatory Affairs/Quality Assurance
Inviro Medical Devices, Incorporated
1755 North Brown Road, Suite 150
Lawrenceville, Georgia 30043

Re: K092430
Trade/Device Name: InviroSnap Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: July 31, 2009
Received: August 7, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Susan Runner, D.D.S., M.A.
Acting Division 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

510(k) Number (if known):_____

Device Name:

Indications For Use:

The InviroSnap Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the InviroSnap Safety Syringe is designed to aid in the prevention of needle stick injuries.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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