K101359

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

Date prepared: April 29, 2010

AUG 2 0 2010

A. Submitter Information

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

Phone Number: 949-433-3058
Fax Number: 949481-5745
Contact: Jim Barley
Director of RA/QA

Trade Name: InviroStripe 1, 3, 5, 10, 20, 30 and 60 ml Standard Luer Lock syringes

B. Device Information

Trade/Proprietary Name:	InviroStripe 1, 3, 5, 10, 20, 30 and 60 ml Standard Luer Lock syringes
Common name of device:	Piston Syringe
Classification Name:	Piston Syringe
Product Code:	80 FMF
Regulatory Class:	II
Classification Number:	880.5860
Reason for 510(k):	Special 510(k) – Change in packaging, expansion of product line and change of contract manufacturer.

C. Predicate Device: InviroStripe 3, 5 and 10 ml Standard Luer Lock syringes

Predicate 510(k) #: K081436

Predicate product code: FMF

D. Device Description

The InviroStripe 1, 3, 5, 10, 20, 30 and 60 ml Standard Luer Lock hypodermic syringes are used to inject medicines and vaccines into, or withdraw fluids from, the body.

The piston syringe is a plastic disposable htpodermic 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 – The plunger is used to aspirate and inject fluids into and out of the syringe.

3 Stopper – The Stopper maintains the fluid in the barrel between the syringe nozzle and the Plunger.

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

The InviroStripe Luer Lock Syringes are sterilized by Ethylene Oxide Gas and supplied sterile in a Blister Pack. One Hundred syringes without needles are packaged in a Dispenser Box. Each Blister Pack, Dispenser Box and Case are 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 InviroStripe Standard Luer Lock Syringes are used to inject medicine or vaccines into, or withdraw fluids from, the body.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the InviroStripe Standard Luer Lock Syringes and the cited predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The intended use of the InviroStripe Standard Luer Lock Syringes are 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.

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, "Single Use Sterile Syringe"
4. ANSI/AAMI/ISO 11135:2007 - "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
5. ISO 11607;2003 – Packaging for terminally sterilized medical devices
6. ISO 10993-4:2006 – Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood

Conclusion:

The InviroStripe 1, 3, 5, 10, 20, 30 and 10 ml Standard Luer Lock Syringes are substantially equivalent to the InviroStripe 3, 5 and 10 ml Standard Luer Lock Syringes in indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

AUG 20 2010

Re: K101359
Trade/Device Name: Inviro Medical Luer Lock Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 30, 2010
Received: August 03, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

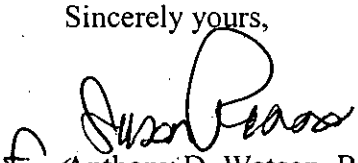
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101359

Indications For Use

510(k) Number (if known): K101359

Device Name: Inviro Medical Luer Lock Syringe

Indications For Use:

The InviroStripe Standard Luer Lock Syringes are used to inject medicines and vaccines into, or withdraw fluids from, the body.

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

Richard C. Chapman

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

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