5. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

Device Information

Trade Name:	PowrSyringe Monitor
Common Name:	Piston Syringe
Classification Name:	FMF Syringe, Piston

Predicate Devices

The PowrSyringe Monitor is substantially equivalent to multiple previous cleared piston, inflation, and pressure monitoring syringes.

Device Description

The PowrSyringe Monitor is a single use manual hand-held piston syringe with handles and a pressure gauge to inject fluids and monitor the pressure of that fluid including use in inflation and discography. The PowrSyringe Monitor handles allow the user to push the plunger into the barrel when the user squeezes the handles. Users may open the PowrSyringe Monitor's handles to aspirate fluid back into the barrel.

The PowrSyringe Monitor safety features include:

- Clear barrel for visualization of air bubbles.
- Minimum dead space between the plunger and barrel with the handles are fully squeezed.
- Handle design to prevent the plunger from being pulled out of the barrel during aspiration.

Intended Use

The PowrSyringe Monitor is a piston syringe to inject fluids and monitor the pressure of that fluid including use in inflation and discography.

Comparison to Predicate Devices

Data is provided to demonstrate the PowrSyringe Monitor is substantially equivalent to previous cleared devices and does not introduce any new safety risks. Substantial equivalence is based on equivalence in indications for use, intended use, patient contact, materials, design, function, performance, sterilization, and safety.

Non-Clinical Testing

Bench and animal performance testing to confirm functionality in the intended use and equivalence to predicate device is included.

Clinical testing

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2007

Pinyons Medical Technology, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street North West
Buffalo, Minnesota 55313

Re: K072345
Trade/Device Name: PowrSyringe Monitor
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 5, 2007
Received: September 6, 2007

Dear Mr. Job:

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.

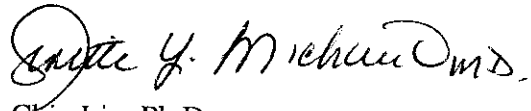
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

4. Indication for Use Statement

510(k) Number: K972345

Device Name: PowrSyringe Monitor

Indications for Use:

The PowrSyringe Monitor is a piston syringe to inject fluids and monitor the pressure of that fluid including use in inflation and discography.

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

Anthony D. Watson

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

510(k) Number: K972345