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**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>PowrSyringe Injector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Piston Syringe</td>
</tr>
<tr>
<td>Classification Name</td>
<td>FMF Syringe, Piston</td>
</tr>
</tbody>
</table>

**Predicate Devices**

The PowrSyringe Injector is substantially equivalent to multiple previous cleared piston syringes and angiographic syringes.

**Device Description**

The PowrSyringe Injector is a single use manual hand-held piston syringe with handles to inject fluids into, or aspirate fluid from, the body including use in angiography. The PowrSyringe Injector handles allow the user to push the plunger into the barrel when the user squeezes the handles. Users may open the PowrSyringe Injector’s handles to aspirate fluid back into the barrel.

The PowrSyringe Injector 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 Injector is a piston syringe to inject fluids into, or aspirate fluids from, the body including use in angiography.

**Comparison to Predicate Devices**

Data is provided to demonstrate the PowrSyringe Injector 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.
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: K072318
  Trade/Device Name: PowrSyringe Injector  
  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” (21 CFR 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/cdrli/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: \[ K\phi 72318 \]

Device Name: PowrSyringe Injector

Indications for Use:

The PowrSyringe Injector is a piston syringe to inject fluids into, or aspirate fluids from, the body including use in angiography.

Prescription Use \( \times \) AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

510(k) Number: \[ K\phi 72318 \]