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PharmaJet®

510(k) Premarket Notification
PharmaJet, Inc.
PharmaJet Needle-free Injection System
-510(k) Summary-

FEB 2 6 2009

Date prepared: 5/30/2008

Device Name – Proprietary, Common, Classification, and Panel

Owner's Name and Address:	PharmaJet, Inc. 221 Corporate Circle Suite D Golden, CO 80401
Device Name – Proprietary:	PharmaJet Needle-free Injector
Device Name – Common and Classification	Injector, Fluid, Non-Electrically Powered (21CFR 880.5430, Product Code KZE, Class II)
Device Panel:	General Hospital

Application Information

Contact:	Ron Bauer
Telephone:	(303) 526-4278
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Establishment Registration Number:	3004977013
Owner/Operator Number:	9063237

Submission Correspondent Information:

Address:	PharmaJet, Inc. 221 Corporate Circle Suite D Golden, CO 80401
Contact:	Ron Bauer
Telephone:	(303) 526-4278

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Reason for Premarket Notification

New Device

Predicate Devices with Associated 510(k) Number

Genesis Medical Technologies, Inc. PharmaJet Needle-free Injector	K041239
Bioject, Inc. Biojector 2000 Needle-free Injection Management System	K960373

Description of Device

The PharmaJet, Inc. PharmaJet Needle-free Injector System (PharmaJet System) is a compact, spring-loaded needle-free hypodermic injector system. The PharmaJet System consists of two (2) injectors (One is the light injector suitable for infants up to two years old, geriatric adults or locations with thin skin and minimal adipose tissue and one is the heavy injector suitable for adults and children two years and older, or locations with thicker skin and more adipose tissue.), a cocking device, a single use, sterile, disposable filling adapter, and a single use, sterile, disposable needle-free syringe.

An injector is placed in the cocking device and the lid is depressed to cock the spring in the injector. The healthcare worker puts a filling adapter into a vial of liquid medicine or vaccine. A needle-free syringe is placed into the filling adapter and the liquid is drawn into the needle-free syringe and is slightly over filled. The plunger is broken off and discarded. With the adapter, needle-free syringe, and vial still engaged the needle-free syringe is placed into the injector with a ¼ turn to the right, this returns excess medicine or vaccine back into the vial and positions the plunger to deliver a 0.5ml dose. The adapter and filled needle-free syringe can now be separated. The needle-free syringe is placed against the injection site, which displaces the safety interlock. By depressing the trigger the spring is released and the plunger moves forward into the needle-free syringe barrel discharging the contents. As the medicine or vaccine passes through the orifice under high pressure, it forms a jet of fluid that penetrates the skin.

Injector
The Injector is a reusable compact spring-actuated needle-free hypodermic injector consisting of the body, inner body/safety collar, trigger, and spring. The injector is made with stainless steel and injection molded amorphous thermoplastic polyetherimide.

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Needle-free Syringe
The Needle-free syringe is a single use, transparent, disposable, polypropylene container consisting of the barrel to hold 0.5ml of medicine or vaccine, a plunger to discharge the medicine or vaccine through a small diameter orifice at the forward end of the barrel, and a silicone seal on the plunger to prevent leakage of the medicine or vaccine rearward.

Cocking Device
The cocking device is used to prepare (cock) the spring, within the injector, for injection. The cocking device is made with stainless steel and injection molded amorphous thermoplastic polyetherimide.

Filling Adapter
The filling adapter allows the needle-free syringe to be filled with medicine or vaccine from medicine or vaccine storage vials.
The filling adapter material, which does not contact the patient, is injection-molded polycarbonate.

Intended Use

The PharmaJet Needle-free Injection System is intended to deliver various medications and vaccines either intramuscularly or subcutaneously by means of a narrow, high velocity fluid jet, which penetrates the skin and delivers the medicine or vaccine to the body. Healthcare providers who routinely administer injections may use the PharmaJet Needle-free Injection System. It may be used for adults and children. It can also be used by patients authorized by their physicians to self inject, or have other individuals administer injections of prescribed medication.

Technological Characteristics

Characteristic	**PharmaJet Needle-free Injection System**	**Genesis Medical Technologies PharmaJet Injector**	**Bioject Biojector 2000**
Trigger safety	Yes	Yes	No
Spring life cycle	20,000	600	N/A
Method of power	Mechanical spring	Mechanical spring	CO_2 compressed gas
Method of spring reset	External cocking device	External cocking device	N/A
Method of medicine and/or vaccine transfer	Filling adapter	Standard needle or other similar device	Filling adapter
Volume:	0.5ml	0.5ml	0.1 to 1.0 ml

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Expelled volume tolerance	± 5%	± 5%	Unknown
Material	Body – polypropylene Plunger – polycarbonate Seal – silicone rubber	Body and plunger– polypropylene	Body - Polycarbonate Plunger - Unknown Seal – Silicone rubber
Orifice Diameter	0.009"	0.007"	0.004 0.006 0.008 0.010 0.014
Disposable	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Sterilization Method	Electron beam radiation	Electron beam radiation	Ethylene oxide

Discussion of the Non-clinical Tests

Pigs have been determined to be predictive models for depth of penetration studies for healthy adults and children two years and older, or locations with thicker skin and more adipose tissue for injection into the deltoid, lateral thigh, or buttocks. Lambs have been determined to be predictive models for depth of penetration studies in infants up to two years old, geriatric adults or locations with thin skin and minimal adipose tissue. Preclinical animal testing using these two animal models have been completed for intramuscular and subcutaneous delivery to demonstrate substantial equivalence to a predicate device. It was found in these tests that the variability in the PharmaJet Injector's depth of penetration is equal to or less than the variability of the Bioject B2000 injector's depth of penetration. Overall there is no difference in accuracy of the two injectors and for subcutaneous injections the PharmaJet injector is more accurate than the Bioject injector.

Bench testing has been completed to establish that the system meets customer requirements for performance and robustness by meeting the essential requirements of *ISO21649:2006 Needle-free injectors for medical use —Requirements and test methods*. These include operating temperature, storage temperature, free-fall, vibration, shock, dose accuracy, life cycle, performance profile upper and lower acceptance limits, and emitted noise.
Maximum irradiated sterility dose test was done on the needle-free syringe to demonstrate material robustness, and microbial ingress testing on the Filling Adapter was done to demonstrate that the Filling Adapter can be disinfected using common disinfection techniques.
Biocompatibility testing conducted demonstrate that the PharmaJet Needle-free Syringe and Filling Adapter meet the requirements for safe short-term exposure.

Functional testing after Glutaraldehyde-based and peroxide-based high level disinfection shows no degradation of performance or damage to Injectors or Cocking Devices

Conclusion

Pre-clinical testing and bench testing have shown that for intramuscular and subcutaneous delivery with needle-free jet injection the PharmaJet Needle-free Injection System is as effective, as safe, and performs as well as or better than one of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ron Bauer
Executive Director of Regulatory and Quality Assurance
PharmaJet, Incorporated
221 Corporate Circle, Suite D
Golden, Colorado 80401

FEB 2 6 2009

Re: K081532
Trade/Device Name: PharmaJet Needle-Free Injection System
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: January 28, 2009
Received: February 2, 2009

Dear Mr. Bauer:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting 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): K 081532

Device Name: PharmaJet, Inc., PharmaJet Needle-free Injection System

Indications for Use: The PharmaJet Needle-free Injection System is intended to deliver various medications and vaccines either intramuscularly or subcutaneously by means of a narrow, high velocity fluid jet, which penetrates the skin and delivers the medicine or vaccine to the body. Healthcare providers who routinely administer injections may use the PharmaJet Needle-free Injection System. It may be used for adults and children. It can also be used by patients authorized by their physicians to self inject, or have other individuals administer injections of prescribed medication.

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

510(k) Number: K081532