JUL 27 2011

Special 510(k) Premarket Notification
PharmaJet®, Inc.
PharmaJet® Stratis Needle-free Injection System

Section 5: 510(k) Summary

510(k) Number: K111517

Date Prepared: 31 May 2011

Device Name – Proprietary, Common, Classification, and Panel

Proprietary:	PharmaJet® Stratis 0.5 mL Needle-free Injection System
Common:	Injector, Fluid, Non-Electrically Powered
Classification:	21 CFR 880.5430; Product Code KZE, Class II
Device Panel:	General Hospital

Application Information

Applicant:	PharmaJet®, Inc. 400 Corporate Circle, Suite N Golden, CO 80401
Telephone:	(303) 526-4278
FAX:	(303) 526-4052
Establishment Registration:	3004977013
Owner/Operator:	9063237

Submission Correspondent Information

Contact:	Michael J. Ryan, R.A. Manager
Telephone:	(303) 526-4278 Ext. 4172

Reason for Premarket Notification

Device modifications

Predicate Device

PharmaJet® 0.5 mL Needle-free Injection System, K081532

Description of the Device

The PharmaJet® Stratis 0.5 mL Needle-free Injection System is a compact, spring-loaded needle-free hypodermic injection system. The PharmaJet® System consists of an injector, a reset station, a single use, sterile disposable filling adapter, and a single use, sterile, disposable needle-free syringe. The components of the system may be sold separately for replacements as they are

used. The components of the PharmaJet® System are unique and cannot be used with any other needle-free system.

The Predicate device, the PharmaJet® 0.5 mL Needle-free Injection system (K081532) is a compact, spring-loaded needle-free hypodermic injection system. The predicate system consists of two (2) injectors; a reset station; a single use, sterile disposable filling adapter; and, a single use, sterile disposable needle-free syringe. The components of the system may be sold separately for replacements as they are used. The components of the PharmaJet® System are unique and cannot be used with any other needle-free system.

Injectors
The Injector is a reusable compact spring-actuated needle-free hypodermic injector consisting of the body, inner body/safety collar, trigger, and spring.

Needle-free Syringes
The Needle-free syringes are sterile, single use, transparent, disposable containers consisting of: the barrel to hold 0.5 mL 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, an o-ring on the plunger to prevent leakage of the medicine or vaccine rearward.

Reset Stations
The Reset Station is used to prepare (reset) the spring, located within the injector, for an injection.

Filling Adapters
The Filling Adapter is a sterile, single use, transparent, disposable, accessory that allows the needle-free syringe to be filled from medicine or vaccine storage vials.

Intended Use

The Stratis Needle-free Injection System is intended to deliver subcutaneous or intramuscular injections of vaccines or medicines.

Indications for Use

The PharmaJet® Stratis 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 to have other individuals administer injections of prescribed medication.

Technological Characteristics

The technological characteristics of the Stratis System are substantially equivalent to the predicate system and are summarized in the table below.

Technological Characteristics Summary		
Characteristic	**PharmaJet® Stratis Needle-free Injection System**	**PharmaJet® 0.5 ml Needle-free Injection System (K081532)**
Injector		
Material	Polycarbonate-ABS	Polyetherimide
Trigger	Ball/Latch trigger	Latch spring trigger
Syringe retainer mechanism	Syringe is pushed into the pawl mechanism	Physical ¼ turn of the syringe
Energy source	Stainless Steel Compression spring	Stainless Steel Compression spring
Spring life cycle	20,000	20,000
Method of spring reset	External resetting device	External resetting device
ISO 21649: 2006 compliant	Yes	Yes
Volume	0.5 mL	0.5 mL
Syringe		
Orifice Diameter	0.010"	0.009"
Tip Ring Diameter	0.329"	0.529"
Barrel	Polycarbonate	Polypropylene
Plunger	Lustran 348 ABS	Polycarbonate
Plunger o-ring	Medical Grade Silicone	Medical Grade Silicone
Disposable	Yes	Yes
Sterile	Yes	Yes
Sterilization Method	Gamma radiation	Electron beam radiation
Filling Adapter		
Material	Polycarbonate	Polycarbonate
O-Ring material	N/A	Medical Grade Silicone
Reset Station		
Material	Polycarbonate-ABS	Polyetherimide

Summary of Non-clinical Bench Tests

The purpose of the Bench Testing for the PharmaJet® Stratis Needle-free Injection System was to establish that the system meets the requirements of the Product and Engineering Specifications with regard to robustness for customer needs and the essential requirements of *ISO21649:2006 Needle-free injectors for medical use —Requirements and test methods.*

The following tests have been successfully completed:

- Temperature, storage temperature, free-fall, vibration, shock, dose accuracy, life cycle, performance profile upper and lower acceptance limits and emitted noise testing according to *ISO 21649: 2006 Needle-free injectors for medical use – Requirements and test methods*
- Needle-free Syringe Irradiated Dose Test for Robustness

Summary of Animal Test

Animal testing was performed to demonstrate substantial equivalence to the predicate device for intramuscular and subcutaneous injections in an animal (pig) model. The test results indicate that the PharmaJet® Stratis Needle-free Injection System has greater depth of penetration than the predicate device for intramuscular injections and is substantial equivalence to the predicate device for subcutaneous injections.

Biocompatibility

Biocompatibility testing demonstrate that the PharmaJet® Needle-free Syringe and Filling Adapter was tested to the ISO 10993 standard and meets the requirements for safe short-term exposure.

Design Control/Risk Analysis/Design Verification & Validation

The design control activities: design inputs, design outputs, risk analysis, and design verification activities for the Stratis Needle-free Injection System have been conducted and prepared in accordance with the applicable PharmaJet® standard operating procedures for design control, ISO 13485, ISO 14971, and 21 CFR 820.30.

Verification and validation testing was formally controlled and included test methods, tests used, and acceptance criteria. Design verification and validation consisted of biocompatibility testing, depth of penetration testing in an ultrasound gel model, and ISO 21649: 2006 Needle-free injector compliance testing. This testing has demonstrated that the design outputs of the device have met the predetermined design input requirements.

Conclusion

The PharmaJet® Stratis Needle-free injection System is of the same inherent technology as the predicate device, the PharmaJet® 0.5 mL Needle-free Injection System. Spring powered injection technology is employed in both the subject and predicate device.

The indications for use for the subject device are equivalent to the indications for use for the predicate device.

The performance characteristics of the Stratis Needle-free Injection System are substantially equivalent to the predicate device and have been verified to meet the requirements defined in design inputs as well as *ISO 21649: Needle-free injectors – for medical use*. Design verification and validation testing has demonstrated the subject device to be substantially equivalent to the predicate device.

Animal test results in a pig model indicate that the PharmaJet® Stratis Needle-free Injection System is substantially equivalent to the PharmaJet® 0.5 mL Needle-free Injection System, K081532.

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. Michael J. Ryan
Regulatory Affairs Manager
PharmaJet, Incorporated
400 Corporate Circle, Suite N
Golden, Colorado 80401

JUL 27 2011

Re: K111517
Trade/Device Name: PharmaJet® Stratis 0.5 mL Needle-free Injection System
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: July 8, 2011
Received: July 11, 2011

Dear Mr. Ryan:

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/ DRHOffices 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

Indications for Use

510(k) Number (if known): K111517

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

Indications for Use: The PharmaJet® Stratis 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 to 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)

Richard C. Chapman 7/26/11
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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