FOR IMMEDIATE RELEASE

PharmaJet® FDA Regulatory Clearances on its Needle-free Injection Devices

GOLDEN, CO, USA - October 21, 2011 3:37pm – PharmaJet has received two FDA 510(k) marketing clearances for its IM/SC injection technology. Below are the INDICATIONS FOR USE, cleared by the FDA.

FDA 510(k) Number K111517: PharmaJet Stratis Needle-free Injection System

"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."

FDA 510(k) Number K081532: PharmaJet Needle-free Injection System

"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 to have other individuals administer injections of prescribed medication."

The concurrence of CDRH, Office of Device Evaluation (ODE) is attached for both of PharmaJet's FDA 510(k) clearances.

About PharmaJet Inc. and Needle-free Injection Technology: PharmaJet's needle-free injection technology delivers drugs and vaccines to intramuscular, subcutaneous and intradermal tissue depths. PharmaJet injectors use pressure to create a fine stream of liquid that penetrates the skin, delivering doses to the desired depth, while eliminating needle-stick risk and the burden of sharps waste management. For more information on PharmaJet's needle-free injection technology, please contact the Company at:

Contact Information: Regina Todd
Communications Manager
PharmaJet, Inc.
todd@pharmajet.com

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)

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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

510(k) Number: K111517

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
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081532