K121270

BIOJECT

BIOJECT INC.
7180 SW Sandburg St.,
Suite 100
Tigard OR, 97223
PH: 503.692.8001
FAX: 503.692.6698
WWW.BIOJECT.COM

PREMARKET NOTIFICATION

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

as required by section 21 CFR 807.92(c)

Date Prepared: April 23, 2012

JUL 19 2012

Submitted By:

Bioject, Inc.
Christine Breitbach
QA/QC/RA Manager
7180 SW Sandburg St., Suite 100
Tigard, OR, 97223, USA
503-692-8001 Phone
503-692-6698 Fax

Device Name:

Proprietary Name: Biojector® 2000 Needle-Free Injection Management System (B2000)

Common Name: Needle-Free Jet Injector

Classification Name: Injector, Fluid, Non-Electrically Powered
21 CFR 880.5430, Product Code KZE

Predicate Device(s): Biojector® 2000 Needle-Free Injection Management System (K960373)

Becton Dickinson Single Use Hypodermic and Insulin Syringe (K980580)

Terumo America, Inc Disposable Hypodermic Needle (K771203)

PharmaJet 0.1 ml Needle-free Injector System (K110456)

Purpose of Submission: To add a new Indication for Use with the Biojector® 2000 to administer intradermal injections using the ID Spacer.

Device Description:

The Bioject® 2000 Needle-Free Injection Management System is designed to deliver vaccines and other pharmaceutical injectables by producing a high pressure injectate stream that penetrates the dermis. The system is composed of three major components: (1) the injector – Biojector® 2000; (2) sterile single use disposables – syringes in multiple orifice sizes, safety cap, filling adapter and intradermal spacer (packaged for use with a No. 2 syringe only); and (3) power source – carbon dioxide (CO_2) cartridge or tank.

The depth of injectate penetration is dependant upon the syringe orifice diameter. In general, the larger the diameter of the syringe orifice, the deeper into the tissue the fluid will be

K121270

deposited. Disposable syringes with a variable volume from 0.1 ml to 1 ml are numbered 2, 3, 4, 5 and 7, and have increasing syringe orifice diameters, 0.04", 0.06", 0.08", 0.10" and 0.14" respectively. Intradermal injections (ID) are only performed using a No. 2 syringe (the smallest diameter) and an ID Spacer. As the distance from the syringe orifice to the skin is increased, the energy density of the fluid stream is decreased. The ID Spacer utilizes this principle to provide the optimum distance from the syringe to the skin to provide enough energy for the injectate to penetrate the epidermis, but not enough energy to transverse the underlying dermal tissue. Subcutaneous (SC) injections are performed using a No. 2 syringe that is in direct contact with the skin, no spacer is utilized. Intramuscular (IM) injections are performed using syringes in contact with the skin and with larger orifice diameters.

The disposable syringe assemblies are provided sterile in a Tyvek blister peel pouch. The ID Spacer is manufactured from a high density polyethylene that meets the same environmental, biocompatibility and sterility requirements as the disposable syringes. The ID Spacer is packaged as a component with Biojector® No. 2 syringe assemblies.

Intended Use:

The Biojector® 2000 is indicated for delivery of subcutaneous (SC), intramuscular (IM) or intradermal (ID) injections of vaccines and other pharmaceutical injectables. The Biojector® 2000 may be used by healthcare providers who routinely administer injections. The Biojector® 2000 may also be used by patients authorized by their healthcare practitioner to self inject, or have other individuals administer injections of prescribed medication.

The addition of the intradermal indication is facilitated by using the new Intradermal Spacer with a No. 2 Syringe. Intradermal injections of vaccines and other pharmaceuticals are performed on the same patient populations that are now being treated with the Biojector® 2000 for the previously cleared indications.

Device Use:

A device operator (healthcare worker, or a patient/family member authorized by their practitioner), aseptically opens the sterile packaging and fills the syringe with a desired amount of liquid medication using the provided disposable vial adapter. The filled syringe is then loaded into the Biojector® 2000 with a clockwise twisting motion until completely seated and a green color is visible in the syringe interlock window. The actuator (trigger) interlock is disengaged and the device is ready for use. The operator presses the syringe (or ID Spacer for intradermal injections) onto the skin at a 90° angle in a location appropriate for the route of administration and the actuator is pulled back initiating the injection. Following the injection, the syringe (and ID Spacer if used) is discarded in a normal medical waste container. The device is ready for reloading and can perform approximately 10 injections per each new CO_2 cartridge. The Biojector® 2000 can also be attached to a large capacity CO_2 tank with an adapter to perform increased numbers of injections between gas source changes.

Non-Clinical Testing Summary

Performance:

The Biojector® 2000 Needle-Free Injection Management System including the Intradermal (ID) Spacer has been verified to meet the performance requirements of ISO 21649:2006, Needle-free injectors for medical use – Requirements and test methods.

K121270

Biological Safety:

The Bioject ID Spacer is a patient contact component and has been tested to, and met the established criteria for, the following biocompatibility requirements:

Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2010
Irritation/Intracutaneous Reactivity	ISO 10993-10:2010

The Biojector® 2000 disposables have patient and drug contact surfaces that are tested to, and met the established criteria for, the following biocompatibility requirements:

Cytotoxicity	ISO 10993-5:2009
Irritation/Intracutaneous Reactivity	ISO 10993-10:2010
Acute Systemic Toxicity	ISO 10993-11:2006
Haemocompatibility	ISO 10993-4:2002/Amd 1:2006

Sterilization:

The final packaged No. 2 Syringe with ID Spacer assembly has been tested to, and met the established criteria for, the following sterilization requirements:

Ethylene Oxide Sterilization	ISO 11135:2007
Ethylene Oxide Residuals	ISO 10993-7:2008

Animal Studies:

Testing in an accepted porcine model was conducted and demonstrated that intradermal injections performed using the Biojector® 2000 with an Intradermal Spacer or with a needle and syringe are substantially equivalent for the criteria tested: 1) wheal size, 2), depth of penetration, and 3) dye dermal contact area.

Technological Comparison:

Characteristic	Biojector® 2000 with ID Spacer	Biojector® 2000 (IM & SC)	BD Syringe and Terumo Needle	PharmaJet O.1 ml NFI System
Actuation	Trigger	Trigger	Standard Piston Syringe & Needle	Trigger
Trigger Safety	Yes	Yes	NA	Yes
Power Source	CO_2 gas	CO_2 gas	Human	Mechanical Spring
Injector Life Cycle	33,000 injections	33,000 injections	NA	20,000 injections
Medication Transfer	Vial Adapter	Vial Adapter	Hypodermic needle	Vial Adapter
ISO 21649:2006 Compliance	Yes	Yes	NA	Yes
Volume of Injectate	0.1 ml only	0.1 ml to 1.0 ml	0.05 ml to 1.0 ml	0.1 ml fixed
Dose Accuracy	± 5%	± 5%	Unknown	± 5%

K121270

Characteristic	Biojector® 2000 with ID Spacer	Biojector® 2000 (IM & SC)	BD Syringe and Terumo Needle	PharmaJet O.1 ml NFI System
Orifice Diameter	0.004"	0.004", 0.006", 0.008", 0.010", 0.014"	NA	0.007"
Single Use Disposables	Yes	Yes	Yes	Yes
Sterile Disposables	Yes	Yes	Yes	Yes
Disposable Sterilization Method	EtO	EtO	Unknown	Electron Beam

Conclusion:

The Biojector® 2000 with the Intradermal Spacer has the same indications for use as the predicate devices and is substantially equivalent to the performance of the PharmaJet 0.1 ml Needle-free Injector System and the use of a needle and syringe for intradermal injections. The Biojector ® 2000 when used with the Intradermal Spacer does not raise any new issues of safety and effectiveness.

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

Ms. Christine Breitbach
QA/QC/RA Manager
Bioject Medical Technologies, Incorporated
7180 SW Sandburg Street, Suite 100
Tigard, Oregon 97223

JUL 19 2012

Re: K121270
Trade/Device Name: Biojector® Needle-Free Injection Management System, Biojector® B2000
Regulation Number: 21 CFR 880.5430
Regulation Name: Non-electrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: April 24, 2012
Received: April 26, 2012

Dear Ms. Breitbach:

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.

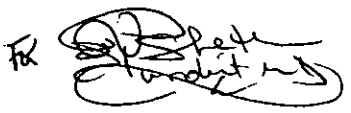
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/CDRHOffices/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

K121270

INDICATIONS FOR USE

510(K) # (if known): _____

Device Name: Biojector® Needle-Free Injection Management System, Biojector® B2000

Indications for Use: The Biojector® 2000 is indicated for delivery of subcutaneous (SC), intramuscular (IM) or intradermal (ID) injections of vaccines and other pharmaceutical injectables. The Biojector® 2000 may be used by healthcare providers who routinely administer injections. The Biojector® 2000 may also be used by patients authorized by their physicians to self inject, or have other individuals administer injections of prescribed medication.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for REC July 18, 2012

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

510(k) Number: K121270