K090003

BIOJECT

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510(k) Summary as required by section 807.92(c)

Submitter Identification:

APR - 2 2009

Bioject Inc.
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Contact Person:
Kris Richard
Quality Assurance/Regulatory Affairs
Email: krichard@bioject.com

Date Prepared:	December 30, 2008
Trade name:	Zetajet Needle-Free Injection Therapy System
Common name:	Needle-free Fluid Jet Injector
Classification name:	Injector, Fluid, Non-Electrically Powered (Class II, KZE, 880.5430)
Predicate Device:	Biojector® 2000 (B2000) Jet Injection System (K960373)

Device Description:

The Zetajet Needle-free Injection Therapy System is a compact, spring-powered, needle-free delivery system. It is intended to deliver vaccines and injectable medications either subcutaneously or intramuscularly. The Zetajet system consists of the injector body and the single-use, sterile syringe assembly with a pre-inserted piston in the syringe. The Zetajet uses jet force to propel a finely dispersed stream of the injectable medication into the subcutaneous or intramuscular tissue.

The disposable assembly consists of a single-use, sterile, disposable syringe designed to contain a volume between 0.05 and 0.5 ml and a plunger to discharge the medicine or vaccine through a syringe orifice size based on the type of injection to be given (either subcutaneous or intramuscular).

Intended Use:

The Zetajet is indicated for delivery of subcutaneous or intramuscular injections of vaccines and other injectable drugs into standard injection sites. The Zetajet may be used by physicians, nurses, veterinarians, podiatrists and other practitioners who routinely administer injections. The Zetajet may also be used by patients authorized by their physicians to self inject, or have other individuals administer injections of prescribed medication.

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Substantial Equivalence:

The Zetajet is as safe and effective as the B2000, the device upon which this 510k demonstrates substantial equivalence. The Zetajet has the same intended use and operational performance as the predicate device. The Zetajet also has many of the same or similar technological characteristics as the predicate device, including the use of different syringe orifice sizes to control the depth of penetration. The technological difference between the Zetajet and its predicate device, namely the use of a spring instead of compressed CO2 gas as the power source, does not raise new questions of safety or effectiveness.

Substantial equivalence is based upon equivalence in intended use, labeling, design, and operational performance to the B2000. The Zetajet is as safe and effective as the legally marketed predicate device, and does not raise questions of safety and efficacy different than that of the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kris Richard
BIOJECT, Incorporated
20245 South West 95th Avenue
Tualatin, Oregon 97062

APR - 2 2009

Re: K090003
Trade/Device Name: Zetajet Needle-free Injection Therapy System
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: February 24, 2009
Received: February 25, 2009

Dear Ms. Richard:

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-. 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): K090003

Device Name: Zetajet Needle-free Injection Therapy System

Indications for Use:

The Zetajet is indicated for delivery of subcutaneous or intramuscular injections of vaccines and other injectable drugs into standard injection sites. The Zetajet may be used by physicians, nurses, veterinarians, podiatrists and other practitioners who routinely administer injections. The Zetajet 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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