



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1997

Mr. Mary K. Norton
Manager, Regulatory Affairs/Quality Assurance
Bioject, Incorporated
7620 S.W. Bridgeport Road
Portland, Oregon 97224

Re: K960373
Trade Name: Biojector 2000 Needle-Free Injection
Management System
Regulatory Class: II
Product Code: KZE
Dated: December 5, 1996
Received: December 6, 1996

Dear Ms. Norton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

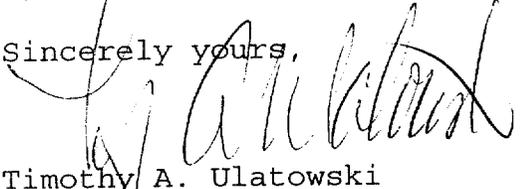
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known) K960373

Device Name: Biojector® Needle-Free Injection Management System,
Biojector® 2000

Indications For Use:

The Biojector® 2000 is indicated for delivery of subcutaneous (SC) or intramuscular (IM) injections of vaccines and other injectable drugs. The Biojector® 2000 may be used by physicians, nurses, veterinarians, podiatrists and other practitioners 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Patricia Ciccone*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 960373

Prescription Use
(Per 21 CFR 801.109)

OR

Over The-Counter Use

Optional Format 1-2-96)

011-1

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K960373

BIOJECT

January 24, 1996

MAR - 5 1997

BIOJECT INC.
7620 S.W. BRIDGEPORT ROAD
PORTLAND, OREGON 97224
TELEPHONE: (503) 639-7221
FAX: (503) 624-9002

510(k) SUMMARY (21CFR Subpart 807.92)

(a)(1) Submitter Identification:

Bioject, Inc.
7620 SW Bridgeport Road
Portland, OR 97224
800-683-7221
503-624-9002 (fax)

Contact Person:
Mary K. Norton
Manager, Regulatory Affairs/Quality
Assurance

- (a)(2) Device Name: Biojector® 2000 Needle-Free Injection Management System™
Common Name: Needleless Injector, Jet Injector
Classification Name: Non-electrically Powered Fluid Injector, 21 CFR 880.5430
- (a)(3) Predicate Device: Biojector® 2000 Jet Injection System (K920631)

(a)(4) Device Description: The Biojector® 2000 is a needle free injection management system designed to deliver drugs both subcutaneously (SC) and intramuscularly (IM). It is a non-electrically powered device which is intended to administer an injection by means of a high velocity jet of fluid that penetrates the surface of the skin and delivers drug to the body. The system is comprised of three major components: The single use sterile medication syringe (medication container), the Biojector® (injector), and the Carbon Dioxide (CO₂) cartridge (power source). The device is also capable of being powered with a CO₂ tank with a specialized adapter.

The syringe holds a variable volume of drug up to a maximum of one cubic centimeter (cc) or milliliter (ml.). Volume increments are marked at 0.10, 0.20, 0.25, 0.30, 0.40, 0.50, 0.60, 0.75, 0.80, 0.90, and 1.0 cc or ml. The syringe is filled using either a fill needle, or a plastic fluid transfer device. Once the syringe is filled, it is loaded in the Biojector®. Syringes are available in five sizes which are numbered 2, 3, 4, 5 and 7. The syringe sizes have the following orifice diameters: 0.004, 0.006, 0.008, 0.010 & 0.014 inches, respectively. The number 2 syringe is used for all subcutaneous injections. The remaining syringes, numbered 3, 4, 5, and 7, are used for intramuscular injections. Depth of penetration of the drug varies with the orifice diameter selected. The larger the orifice diameter, the deeper the penetration of the drug.

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Activation of the Biojector® is initiated when the actuator is depressed. CO2 gas is released, through the action of a series of valves within the injector. This causes the plunger to push the drug out of the sterile syringe, through the syringe orifice at a high velocity, allowing it to penetrate the skin and be deposited in the tissue. Exhaust CO2 is expelled, through the exhaust and bleed valves, in the rear section of the Biojector®, as well as into the cartridge compartment. The CO2 does not come in contact with the drug.

(a)(5) Intended Use: The Biojector® 2000 Needle-Free Injection Management System™ which is the subject of this submission and the currently marketed (predicate) Biojector® 2000 Jet Injection System (with tank adapter), K920631, are intended to deliver subcutaneous (SC) or intramuscular (IM) injections of vaccines and other injectable medications. Both the Biojector® 2000 (subject of submission) and the predicate device may be used by physicians, nurses, veterinarians, and podiatrists and other practitioners who routinely administer injections. The Biojector® 2000 (subject of submission) may also be used by patients authorized by their physicians to self inject at home, or have other individuals administer injections of prescribed drug. It should be noted that a prior submission made by Bioject (K861687), predicate to K920631, was cleared via the 510(k) process for professional and home use.

(a)(6) This Premarket Notification describes modifications to the Biojector® 2000 device previously described via the 510(k) process (K920631). A summary of these modifications includes:

- Changing from a two piece to a one piece main body design with related minor design changes to ease manufacturing;
- Incorporation of design modifications to the exhaust and bleed valves to improve CO2 efficiency and performance;
- Changes in material involved replacing metal parts with plastic parts for cost reduction purposes and to add alternate vendors for existing materials;
- Labeling revisions including the addition of a Home Use Instruction Manual.

There are no changes in intended use or operational principle. Substantial equivalence is based upon equivalence in intended use, labeling, design, materials and operational principle to the Biojector® Jet Injection System (with tank adapter), K920631 and there are no new safety and efficacy issues as a result of the design modifications.

Product qualification testing and biocompatibility data for the modified device (subject of submission) and the current, predicate device (K920631), demonstrate the new model to be functionally equivalent to the predicate device. The device 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.