K042314

NOV 2 2 2004

510(K) SUMMARY
August 25, 2004

8.0 Summary of Safety and Effectiveness

8.1 Submitter's Name and Address: Biogen Idec Inc.
14 Cambridge Center
Cambridge, MA 02142

Contact Person: Victor J. Gangi
Tel: 1-617-679-6238
Fax: 1-617-679-3170

8.2 Trade/Proprietary Name: Syringe Grip for the AVONEX pre-filled syringe
8.3 Common/Usual Name: Injection Assist Device
8.4 Classification Name: Syringe, Piston (Accessory)

8.5 Substantial Equivalence: Substantial Equivalence: The Syringe Grip for the AVONEX pre-filled syringe is substantially equivalent to the Invisiject reusable auto-injector (K032425) and the Carpuject syringe holder (K820164).

8.6 Description: The Syringe Grip for the AVONEX pre-filled syringe is a reusable, grip/handle that is designed to assist the user with the Intramuscular injection of 0.5 mL of AVONEX from a pre-filled syringe and single lumen hypodermic needle. The syringe is securely snapped into the one-piece plastic grip/handle for the primary purpose of providing patients more surface area, hence leverage, with which to hold the syringe while performing manual injections. Using the Syringe Grip for the AVONEX pre-filled syringe instead of direct injection with the pre-filled syringe offers the patient a more comfortable and ergonomic handle to more easily hold and inject the drug. The AVONEX pre-filled syringes and commercially available single lumen hypodermic needles are provided separately.

8.5 Intended Use: The Syringe Grip for the AVONEX pre-filled syringe is a single use device intended to be used by the patient to assist with the self-administered injection of a fixed dose of AVONEX from a pre-filled syringe through a single lumen hypodermic needle. The devices are intended to be used in any setting including the home and are reusable.

8.6 Technological Characteristics: The technological characteristics of the Syringe Grip for the AVONEX pre-filled syringe differ from the predicate device in as much as it is a manual versus spring assist device.

8.7 Performance Data: The device has no functional requirements so performance data is not applicable. The device is designed to securely capture the syringe.

8.8 Conclusion: Biogen Idec concludes based on the information presented that the Syringe Grip for the AVONEX pre-filled syringe is substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

Ms. Nadine D. Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
Biogen Idec Incorporated
14 Cambridge Center
Cambridge, Massachusetts 02142

Re: K042314
Trade/Device Name: Syringe Grip for the AVONEX Pre-filled Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: October 22, 2004
Received: October 28, 2004

Dear Dr. Cohen:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
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 : K042314

Device Name: Syringe Grip for the AVONEX Pre-filled Syringe

Indications For Use:

The Syringe Grip for the AVONEX prefilled syringe is a reusable device indicated for use by the patient to assist with the self-administered injection of a fixed dose of AVONEX from a prefilled syringe through a single lumen hypodermic needle. The devices are intended to be used in any setting including the home.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K042314