K041084

JUL 1 5 2004

Exhibit I

510(k) Summary
Rebif® Clip-On Spacer

Serono, Inc.
One Technology Place
Rockland, MA 02370

1. ***Contact Person:***

Pamela Williamson Joyce
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2. ***Date Summary Prepared:*** April 2, 2004

3. ***Device Information:***

Proprietary Name:	Clip-On Spacer
Common Name:	Manual Titration Clip for Piston Syringe
Classification Name:	Syringe, Piston
Regulatory Class:	Class II by 21 CFR §880.5860
Product Code:	FMF

4. ***Device Description and Performance:***

The Clip-On Spacer is designed to clip around the plunger rod of the Rebif® pre-filled syringe. It is held in place using a hook-hole closure which resists opening, once closed, under axial compression of 28N. When the plunger rod is depressed into the syringe barrel, the Clip-On Spacer limits the volume of solution delivered from the syringe to within ± 1.5% of the syringe volume (1 mL) ± 2% of the expelled volume according to EN ISO 7886-1:1997 "Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use"..

5. ***Substantial Equivalence:***

The substantial equivalence of the Clip-On Spacer for injection of solution from pre-filled Rebif® syringes to manual titration is shown by its similarity intended use, design, materials, and performance characteristics.

6. ***Indications for Use:***

The Clip-On Spacer is intended only for use with pre-filled syringes containing 22 mcg/0.5 mL or 44 mcg/0.5 mL of Rebif®, during the titration stage of treatment. The spacer clips onto the plunger of the syringe so that the distance which the plunger inserts into the barrel when depressed is controlled.

Instructions for use are provided with the Rebif® pre-filled syringe for manual titration with the syringe. These instructions cover all aspects of the treatment regime and are not affected by use of the Clip-On Spacer. The Clip-On Spacer is simply an accessory provided to assist the user in injecting a portion of the Rebif® pre-filled syringe. The use of the Clip-On Spacer during injection of Rebif® in no way affects the treatment regime approved by FDA under BLA STN BL 103780/0.

7. ***Comparison:***

The features of the Clip-On Spacer used during injection of solution from a pre-filled Rebif® syringe versus manual injection are compared in the following Table 2:

Table 2. Comparison of Rebif® Clip-On Spacer to Manual Injection using Rebif® Pre-filled Syringe

	Manual injection of Rebif® from Pre-filled Syringes using the Clip-On Spacer	*injection of Rebif® with Rebiject II™ device from Pre-filled Syringes using the Clip-On Spacer*	*Manual Injection of Rebif® from Pre-filled Syringes*
DESIGN			
Solution provided in syringe exceeds required volume for titration phase	Yes	Yes	Yes
User depresses plunger rod to calibration appropriate mark on syringe barrel	No (Clip-On Spacer stops the plunger rod at the correct titration volume)	No (Clip-On Spacer stops the plunger rod at the correct titration volume)	Yes (visually)
Plunger rod is limited to pre-determined depth within syringe barrel	Yes	Yes	No
INTENDED USE			
Facilitate injection of less than the full volume of a pre-filled syringe	Yes	Yes	Yes
MATERIALS			
Appropriate materials for degree of patient contact	Yes	Yes	Yes

8. ***Non-clinical Performance Data:***

The Clip-On Spacer has been tested for volume delivery accuracy, force and drop testing and risk analysis. The accuracy of volume delivered was within ±1.5% of the syringe volume (1 mL) and ±2% of the expelled volume in accordance with EN ISO 7886-1:1997. The Clip-On Spacer is able to bear axial compression of 28N (14N x 2) without deforming or opening the hook-hole closure. The rigidity of the Clip-On Spacer and the sturdiness of the closing system are strong enough to take a fall of 1 meter on a hard ground without any impact on the safety of the closing system. The results of a risk analysis performed according to ISO/EN 1441 indicated that there is no risk inherent in using the Clip-On Spacer and there are no additional hazards induced with the injection of Rebif® with the spacers compared to manual titration.

9. ***Clinical Performance Data:***

None presented at this time.

10. ***Conclusion:***

The Clip-On Spacer is an accessory provided to assist the user in injecting a portion of the Rebif® pre-filled syringe according to the treatment regime. The Clip-On Spacers accurately deliver the titrated dose required. The use of the Clip-On Spacer during injection of Rebif® in no way affects the treatment regime approved by FDA under BLA STN BL 103780/0.

11. ***Additional Information:***

None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2004

Ms. Pamela Williamson Joyce, RAC
Vice President, Regulatory Affairs & Quality Assurance, US
Serono, Incorporated
One Technology Place
Rockland, Massachusetts 02370

Re: K041084
Trade/Device Name: Clip-on Spacer
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 23, 2004
Received: April 26, 2004

Dear Ms. Williamson Joyce:

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 (301) 594-4618. 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,

Susan Runner

for 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 (if known): K041084

Device Name: Clip-on Spacer

Indications for Use:

The Clip-On Spacer is designed for use with Rebif® pre-filled syringes containing 22 mcg/0.5 mL and 44 mcg/0.5 mL of Rebif® during the dose titration stage of therapy.

The Clip-On Spacer is designed to aid the user in injecting the appropriate percentage of the total volume contained within the syringe, when less than the full volume of the syringe is prescribed.

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)

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

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