K053188

MAY - 4 2006

510(K) SUMMARY

Submitter: SterilMed, Inc.

Contact Person:
Dr. Bruce Lester
SterilMed, Inc.
11400 73rd Avenue North
Minneapolis, MN 55369

Date Prepared: November 14, 2005

Trade Name: Reprocessed Balloon Inflation Device

Classification Name: Injector and Device, Angiographic, Balloon Inflation, Reprocessed

Classification Number: Class II; 870 1650

Product Code: NKU

Predicate Device(s): The SterilMed Reprocessed Balloon Inflation Device is substantially equivalent to the Encore 26 Inflation Device manufactured by Boston Scientific (K955869 cleared March 22, 1996).

Device Description: The Reprocessed Balloon Inflation Device consists of a threaded plunger, locking mechanism, pressure gauge, Device and connecting tube. A finger latch controls the locking mechanism on the device. When the device is unlocked the threaded plunger may be advanced or withdrawn. Locking of the device allows for generation and monitoring of pressure in atmospheres (atm) and pounds per square inch (psi).

Intended Use:

The reprocessed Balloon Inflation Device is intended for use with balloon dilatation catheters to create and monitor pressure in the balloon and to deflate the balloon.

Functional and Safety Testing:

Representative samples of reprocessed Balloon Inflation Devices underwent bench testing to demonstrate appropriate functional performance. Process validation testing was performed to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

The Reprocessed Balloon Inflation Device is substantially equivalent to the Encore 26 Inflation Device manufactured by Boston Scientific (K955869 cleared March 22, 1996). This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2006

SterilMed, Inc
c/o Mr. Dennis Toussaint
Regulatory Affairs Director
11400 73rd Avenue North, Suite 100
Maple Grove, Minnesota 55369

Re: K053188
Trade/Device Name: Reprocessed Balloon Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: NKU
Dated: April 25, 2006
Received: April 26, 2006

Dear Mr. Toussaint:

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) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Model(s): Boston Scientific Encore 26 Inflation Device

INDICATIONS FOR USE

K053188

Device Name: Reprocessed Balloon Inflation Device

Indications for Use:

The reprocessed Balloon Inflation Device is intended for use with balloon dilatation catheters to create and monitor pressure in the balloon and to deflate the balloon.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmer

Division Sign-Off)
Division of Cardiovascular Devi

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