K120694

APR - 3 2012

510(k) Summary
per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation One Boston Scientific Place Natick MA 01760
Contact Person:	Adrienne Hotchkiss
Phone Number:	763-255-0334
Fax Number:	763-494-2222
Prepared:	05 March 2012
Trade Name:	Encore™ 26 Advantage Kit
Common Name:	Balloon Inflation Kit Common name of the kit components: inflation device, insertion tool, Y-adaptor, and torque device
Classification:	II
Product Code:	MAV 21 CFR Part 870.1650
Predicate Device:	Encore™ Advantage Kit (K951802; 21 July 1995)

Device Description:

The Encore™ 26 Advantage Kit is a kit of sterile disposable devices intended for use as accessories for percutaneous coronary angiography (PTCA) procedures. They allow for balloon inflation and wire control.

The proposed Encore™ 26 Advantage Kit will include the following currently marketed devices: Boston Scientific (BSC) Encore Inflation Device (K955869); BSC GateWay™ PLUS Y-Adaptor (K951089); Navilyst Medical TD2® Torque Device (K922706); and NeedleTech Products, Inc. Guidewire Insertion Needle (K031173).

Intended Use

The Encore™ 26 Advantage Kits are intended for use as accessories for percutaneous coronary angiography (PTCA) procedures. They create and monitor balloon inflation and facilitate wire introduction and control.

Individual Device Intended Use:

- Encore™ 26 Inflation Device: Used with balloon dilatation catheters to create and monitor pressure in the balloon, and to deflate the balloon.
- GateWay™ Plus Y-Adapter: Used for providing hemostasis around guidewires, balloon dilatation catheters, and other therapeutic devices.
- TD2® Torque Device: Used for guidewire manipulation.
- Guidewire Insertion Tool: Used for percutaneous introduction and placement of guidewires in vascular procedures.

Substantial Equivalence

The proposed Encore™ 26 Advantage Kit design, materials, manufacturing process and intended use are substantially equivalent to the currently marketed Encore™ Advantage Kit (K951802).

Summary of Non-Clinical Testing

Design verification included mechanical bench testing was performed to verify the performance and usability of the guidewire insertion tool remains substantially equivalent to the guidewire insertion tool in the predicate kit. Biocompatibility, sterility, and packaging testing were also performed to verify the overall safety and efficacy of the device.

Specifically the following design verification and validation testing was performed:

- I.D. (Guidewire Compatibility)
- Hub Tensile Strength
- Biocompatibility Testing
    - Cytotoxicity
    - Sensitization
    - Irritation Or Intracutaneous React
    - Systemic Toxicity (Acute)
    - Hemocompatibility
    - Latex
    - USP Physicochemical

Summary of Clinical Testing

Clinical Evaluation was not required for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 3 2012

Boston Scientific Corporation
c/o Ms. Adrienne Hotchkiss
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K120694
Encore™ 26 Advantage Kit
Regulation Number: 21 CFR 870.1650
Regulation Name: Syringe, balloon Inflation
Regulatory Class: Class II
Product Code: MAV
Dated: March 5, 2012
Received: March 7, 2012

Dear Ms. Hotchkiss:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K120694

Device Name: Encore™ 26 Advantage Kit

Indications For Use:

The Encore™ 26 Advantage Kit is a kit of sterile disposable devices intended for use as accessories for percutaneous coronary angiography (PTCA) procedures. They allow for balloon inflation and wire control.

- Encore™ 26 Inflation Device: Inflation Devices are indicated for use with balloon dilatation catheters to create and monitor pressure in the balloon, and to deflate the balloon.
- GateWay™ Plus Y-Adapter: Used for providing hemostasis around guidewires, balloon dilatation catheters, and other therapeutic devices.
- TD2® Torque Device: Used for guidewire manipulation.
- Insertion Tool: Used for percutaneous introduction and placement of guidewires in vascular procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(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)

M. A. Villalobos

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120694