AUG - 6 2004

510 (k) SUMMARY

SPONSOR:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

CONTACT PERSON:

Paige K. Sweeney
Senior Regulatory Affairs Specialist

DEVICE:

Trade Name: DualFlex™ RX ERCP Cannula
Common Name: Injection Cannula
Classification: Class II, per 21 CFR Part 876, Section 1500

PREDICATE DEVICE:

Boston Scientific Tandem™ RX ERCP Cannula (K970054).

DESCRIPTION:

The DualFlex™ RX ERCP Cannula is a rapid exchange wire-guided catheter used to cannulate and for delivery of contrast media in the biliary duct.

INTENDED USE:

The DualFlex™ RX ERCP is indicated for use to cannulate and inject contrast media to obtain a cholangiogram of the biliary duct system. The contrast media is injected through the cannula and fluoroscopy or x-ray is performed to obtain the cholangiogram.

COMPARISON OF CHARACTERISTICS:

The modified device is substantially equivalent to the predicate device, as they have the same operating principal and intended use. In addition, the results of design control activities do not raise any new issues of safety or effectiveness.

PERFORMANCE DATA:

FDA's "Guidance for the Content of Premarket Notifications", and the results of physical comparison and functional testing support a determination of substantial equivalence for the modified device when compared to the predicate device(s). The modified device is substantially equivalent to the currently

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2004

Ms. Paige Sweeney
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
Microvasive Endoscopy
One Boston Scientific Place
NATICK MA 01760-1537

Re: K041827
Trade/Device Name: Dualflex™ RX ERCP Cannula
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 GCJ
Dated: July 6, 2004
Received: July 7, 2004

Dear Ms. Sweeney:

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); 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number K041827

Device Name DualFlex™ RX ERCP Cannula

Indications For Use Indicated for use to cannulate and inject contrast media to obtain a cholangiogram of the biliary duct system. The contrast media is injected through the cannula and fluoroscopy or x-ray is performed to obtain the cholangiogram.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041827