DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Boston Scientific Corporation
% Mr. Neil E. Devine
Sr. Staff Engineer
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, MA 01719

JUL 27 2005

Re: K051504
Trade/Device Name: SpyScope™ Access and Delivery Catheter
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED, GCJ, FBN
Dated (Date on orig SE ltr): June 2, 2005
Received (Date on orig SE ltr): June 7, 2005

Dear Mr. Devine,

This letter corrects our substantially equivalent letter of June 16, 2005.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): To be determined

Device Name: SpyScope Access and Delivery Catheter

Indications For Use:

The SpyScope Access and Delivery Catheter is intended to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the biliary system including the hepatic ducts.

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)

Nancy C. Brogdon

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K051504

K051504

Boston Scientific

JUN 16 2005

SECTION 10
510(K) SUMMARY

## 510(K) SUMMARY

**1. Submitter:**

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
Owner/operator #9912058

Contact: Jennifer Johnson
Sr. Regulatory Specialist
Boston Scientific Marlborough
100 Boston Scientific Way
Marlborough, MA 01752
Phone: 508-683-4178, Fax: 508-683-5939
Date Prepared: May 16, 2005

**2. Device:**

Trade Name: SpyScope Access and Delivery Catheter
Common Name: Catheter
Classification Name: Endoscopes and Accessories

**3. Predicate Device:**

Olympus SwingTip Cannula, K011149
Olympus CHF Type BP30 Choledochofiberscope, K944473

**4. Device Description:**

The SpyScope Access and Delivery Catheter is a sterile, single-use device comprised of two main components: a flexible delivery catheter and a handle. The device is intended to be used to guide both the SpyGlass Direct Visualization Probe (K050403) or other visualization devices and accessory devices, (such as biopsy forceps, cytology brushes, stone retrieval baskets, etc.) during endoscopic retrograde cholangiopancreatography (ERCP) procedures. The SpyScope Access and Delivery Catheter is introduced to the desired anatomical location through a duodenoscope with a minimum working channel diameter of 4.2mm. The distal tip of the SpyScope Access and Delivery Catheter is designed to articulate in four directions.

**5. Intended Use:**

The SpyScope Access and Delivery Catheter will be intended to guide both optical and accessory type devices for diagnostic and therapeutic applications during endoscopic procedures in the biliary system including the hepatic ducts.

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**6. Technological Characteristics:**

Technological similarities between the SpyScope Access and Delivery Catheter and the Olympus SwingTip Cannula include the articulating tip and between the SpyScope Access and Delivery Catheter and the Olympus Choledochofiberscope includes the working channel, control knobs, and locking mechanism to hold tip in position. In instances where the technological characteristics may differ, it has been demonstrated that there are no new questions raised regarding safety and effectiveness of the SpyScope Access and Delivery Catheter.

**7. Performance Data:**

Bench testing was conducted to evaluate the design features of the SpyScope Access and Delivery Catheter and establish specifications of the descriptive characteristics for the proposed device. These specifications were used to demonstrate substantial equivalence of the proposed device to the predicate devices.

**8. Conclusion:**

BSC has demonstrated that the SpyScope Access and Delivery Catheter is substantially equivalent to Olympus's currently marketed SwingTip Cannula and Olympus's currently marketed CHF Type BP30 Choledochofiberscope.