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. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
70 Codman Hill Road
Boxborough, MA 01779

JUL 27 2015

Re: K050403
Trade/Device Name: SpyGlass Direct Visualization Probe
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODF, FDT
Dated (Date on orig SE ltr): February 15, 2005
Received (Date on orig SE ltr): February 17, 2005

Dear Mr. Lehtonen,

This letter corrects our substantially equivalent letter of March 4, 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

SECTION 4
INDICATIONS FOR USE

510(k) Number: To Be Determined K050403

Device Name: SpyGlass Direct Visualization Probe

Indication for Use:

The proposed SpyGlass Direct Visualization Probe is intended to provide direct visualization for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091)
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative
and Neurological Devices

K050403

K050403

MAR 4 - 2005

SECTION 11
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Contact: Kathleen Morahan
Regulatory Affairs Manager
Date Prepared: January 7, 2005

2. Device:

Trade Name: SpyGlass™ Direct Visualization Probe
Common Name: Mini-Endoscope
Classification Name: Flexible Endoscope

3. Predicate Devices:

Boston Scientific, Visicath Imaging Catheter - K850393
5 Star Medical, Saratoga Modular Miniature Endoscope - K963354

4. Device Description:
The proposed SpyGlass™ Direct Visualization Probe a fiberoptic endoscope. There is a glass lens at the distal end of the probe, and an adapter at the proximal end. The adapter has a bayonet fitting and a light post. An ocular lens connects to the bayonet fitting and the light post provides a connection for a light source. The proposed device is used with an ERCP cannula that provides stability for steering the device. The canula/probe is inserted into the working channel of a duodenoscope for entry into the duodenum and access to the pancreatico-biliary system.

5. Intended Use:
The proposed SpyGlass™ Direct Visualization Probe is intended to provide direct visualization for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

6. Technological Characteristics:
Essentially, the SpyGlass™ Direct Visualization Probe has the same technological characteristics as the predicate devices. The proposed device and both predicate devices are fiberoptic mini-scopes used in conjunction with a mother scope to access and visualize an indicated location.

7. Performance Data:
A comparison of the optical performance and image quality specifications was made between the proposed and predicate Visicath Imaging Catheter. Electrical safety testing was performed in accordance with industry standards.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed SpyGlass™ Direct Visualization Probe is substantially equivalent to the Boston Scientific Visicath Imaging Catheter and in terms of the proposed indication, to the 5 Star Medical Saratoga Modular Miniature Endoscope.