Boston Scientific

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Endoscopy

AUG 2 4 2005

SECTION 11
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

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

Contact: Allyson Barford
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: (508) 683-4356
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Date Prepared: July 8, 2005

2. Device:

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

3. Predicate Devices:

Boston Scientific, SpyGlass Direct Visualization Probe – K050403

4. Device Description:

The proposed SpyGlass Direct Visualization Probe a fiberoptic endoscope. The proposed device is used through the SpyScope Access and Delivery Catheter (K051504) which provides stability for steering the device. The delivery catheter/probe is inserted into the working channel of a duodenoscope for entry into the duodenum for access to the indicated site.

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:

The SpyGlass Direct Visualization Probe is a modification to the predicate device and has the same technological characteristics as the predicate device. The proposed device and predicate device are fiberoptic mini-scopes used in conjunction with a mother scope to access and visualize an indicated location.

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7. Performance Data:

A comparison of the optical performance and image quality specifications was made between the proposed and predicate SpyGlass™ Direct Visualization Probe. 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 predicate SpyGlass Direct Visualization Probe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2005

Boston Scientific Corporation
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K052194
Trade/Device Name: SpyGlass™ Direct Visualization Probe
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: August 10, 2005
Received: August 11, 2005

Dear Mr. Lehtonen:

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) 276-0115. 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/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE

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510(k) Number: ~~To Be Determined~~ K052194

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 Sign-Off)
Division of General, Restorative, and Neurological Devices

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