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
Microvasive Endoscopy
Ms. Lisa M. Quaglia
Regulatory Affairs Manager
One Boston Scientific Place
Natick, MA 01760-1537

JUL 27 2015

Re: K010993
Trade/Device Name: Alien™ RX Micro Cannula, Model 4530
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODD
Dated (Date on orig SE ltr): April 2, 2001
Received (Date on orig SE ltr): April 3, 2001

Dear Ms. Quaglia,

This letter corrects our substantially equivalent letter of April 30, 2001.

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

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Indications for Use Statement

510(k) Number (if known) K010993

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Device Name Alien™ RX Micro Cannula

Indications for Use The Alien™ RX Micro Cannula is indicated for use to cannulate and inject contrast media into the biliary and pancreatic ductal systems. Contrast medium is injected through the cannula and fluoroscopy or x-ray is performed to obtain a cholangiogram.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010993

APR 3 0 2001

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Section 9
510(K) SUMMARY

K010993

Provided in accordance with 21 CFR 807.92

SPONSOR:

Boston Scientific Corporation (BSC)
Microvasive Endoscopy Division
One Boston Scientific Place
Natick, MA 01760

CONTACT/SUBMITTER:

Lisa Quaglia
Regulatory Affairs Manager
Tel: 508-650-8267

DATE OF SUBMISSION:

April 2, 2001

DEVICE:

Alien™ RX Micro Cannula

Trade Name: Alien™ Micro Cannula
Common Name: Cannula
Classification: Endoscope and Accessories
Classified Under 21 CFR Part 876, Section 1500.
Classified as a Class II Device.

PREDICATE DEVICE:

Contour™ ERCP Cannula
(K833417, ERCP Cannula)

DEVICE DESCRIPTION:

The proposed Alien™ RX Micro Cannula is a single lumen cannula. It is compatible with the Boston Scientific Microvasive Endoscopy's Rapid Exchange™ platform, and is capable of accommodating a .025" guidewire while passing through a .035" lumen.

INTENDED USE:

The Alien™ RX Micro Cannula is intended for use to cannulate and inject contrast media into the biliary and pancreatic ductal systems. Contrast medium is injected through the cannula and fluoroscopy or x-ray is performed to obtain a cholangiogram.

COMPARISON OF CHARACTERISTICS:

The proposed device is substantially equivalent to currently marketed devices used for cannulation and injection of contrast media into the biliary and pancreatic ductal systems.

PERFORMANCE DATA:

The proposed device is substantially equivalent to currently marketed ERCP cannulating devices in terms of performance characteristics tested and biocompatibility.