

**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.



APR 3 0 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvative Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K010993
Alien™ RX Micro Cannula, Model 4530
Dated: April 2, 2001
Received: April 3, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Special 510(k) Premarket Notification
Alien™ RX Micro Cannula
March 30, 2001

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Indications for Use Statement

510(k) Number (if known) K 010993

Page 1 of 1

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 (Per 21 CFR 801.109)

OR

Over the Counter Use

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 010993



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2001

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvase Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K010993
Alien™ RX Micro Cannula, Model 4530
Dated: April 2, 2001
Received: April 3, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Ms. Quaglia:

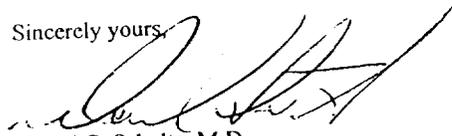
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Sincerely yours,


Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Special 510(k) Premarket Notification
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March 30, 2001

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over the Counter Use

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K 010993

Memorandum

From: Reviewer(s) - Name(s) Mary J. Cornelius
Subject: 510(k) Number K 010993
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
 - Requires additional information (other than refuse to accept).
 - Is substantially equivalent to marketed devices.
 - NOT substantially equivalent to marketed devices.
- De Novo Classification Candidate? YES NO

- Other (e.g., exempt by regulation, not a device, duplicate, etc.) YES NO
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:
Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
 A 510(k) summary OR A 510(k) statement
 The required certification and summary for class III devices N/A
 The indication for use form (required for originals received 1-1-96 and after)
Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

II K09-876.1500

Review: [Signature]
(Branch Chief)

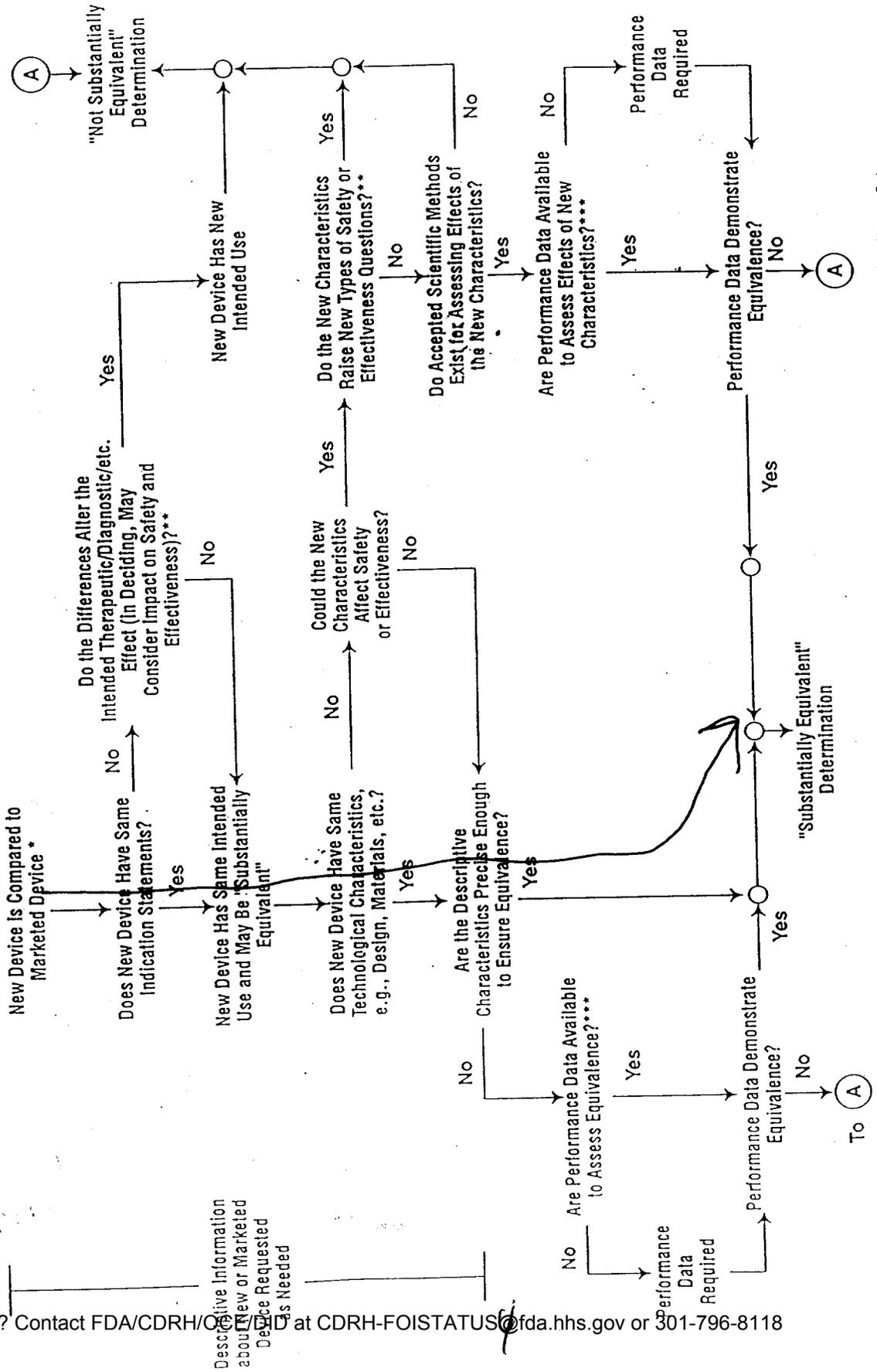
ULDB
(Branch Code)

4/27/01 (Date) (JMC)

Final Review: [Signature]
(Division Director)

4/27
(Date)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH/OCE/DMD at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amended, or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Information is Sometimes Required.

*** Data May Be Required in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

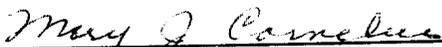
**SPECIAL 510(k): Device Modification
ODE Review Memorandum**

To: THE FILE **RE:** DOCUMENT NUMBER K010993 Alien™ RX Micro Cannula

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) **Contour™ ERCP Cannula K833417 & Rapid Exchange™ ERCP Cannula K970054**
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATIONS**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
This change was for minor dimensional specifications, materials of the shaft and luer connection, and the addition of a latex caution to the labeling.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications. (**Section 4, page 7**)
5. A **Design Control Activities Summary** which includes: (**Section 5, page 8**)
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. (**Section 8, page 12**)
6. A **Truthful and Accurate Statement**, (**Section 10, page 14**) a **510(k) Summary** (**Section 9, page 13**) and the **Indications for Use Enclosure** (**Appendix D, page 34**)

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modifications and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.



(Reviewer's Signature)

April 24, 2001
(Date)

Comments

revised:3/27/98

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**DRAERD REVIEWER RECORD FOR ORIGINAL 510(KS),
AND PMA AND IDE SUPPLEMENTS**

Document No. _____ Reviewer _____ Date Assigned _____

*CONSULTING REVIEWS DESIGNATED, AS APPROPRIATE, BY BRANCH CHIEF AND LEAD REVIEWER,
AT THE BEGINNING OF THE REVIEW:*

<u>SPECIALTY</u>	<u>REVIEW NEEDED?</u>		<u>REVIEWER</u>	<u>DATES</u>	
	YES	NO		SENT	RETURNED
CLINICAL	_____	_____	_____	_____	_____
ENGINEERING/ PHYSICS	_____	_____	_____	_____	_____
CHEMISTRY/ BIOMATERIALS	_____	_____	_____	_____	_____
SOFTWARE	_____	_____	_____	_____	_____
BIOLOGICAL/ STERILITY	_____	_____	_____	_____	_____
TOXICOLOGY/ BIOCOMPATIBILITY	_____	_____	_____	_____	_____
STATISTICS	_____	_____	_____	_____	_____
OTHER _____	_____	_____	_____	_____	_____

COMMENTS:

**REVISED 1/2/96 LMS
ON LAN AS REVREC.FRM**

QUALITY CONTROL OVERVIEW OF DOCUMENT

A. ASSOC. DIRECTOR QC OVERVIEW: MEDICAL QC OF SUBMISSION IS NECESSARY?

YES _____ NO _____ INITIALS/DATE _____

B. IF YES IS NOTED ABOVE, MEDICAL OFFICER QC OVERVIEW:

1. Examination of the specialty reviews indicate there are remaining clinical issues that should be addressed (See attached sheet for summary).

INITIALS/DATE _____

2. In my opinion, all pertinent clinical issues have been adequately addressed.

FINAL SIGNOFF: MEDICAL OFFICER/DATE _____

FINAL SIGNOFF: ASSOC. DIRECTOR/DATE _____

REVISED: 1/2/96 LMS
LOCATED ON LAN AS REVREC.FRM

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 03, 2001

BOSTON SCIENTIFIC CORP.
MICROVASIVE ENDOSCOPY
ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
ATTN: LIAS M. QUAGLIA

510(k) Number: K010993
Received: 03-APR-2001
Product: ALIEN RX MICRO
CANNULA, MODEL 4530

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**Boston
Scientific
MICROVASIVE**

Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508.650.8000
www.bsci.com

April 2, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Special 510(k) Premarket Notification for ERCP Cannulas – K833417

Dear Madam/Sir,

Pursuant to 21 CFR 807.90(c), Boston Scientific Corporation is submitting two copies of the Special 510(k) Premarket Notification for a proposed medical device that is a modification to out legally marketed ERCP Cannula cleared by the FDA via 510(k) K833417.

As evidenced by the information contained herein, the proposed Alien™ RX Micro Cannula device is “substantially equivalent” to the ERCP Cannula. A Special 510(k) Premarket Notification is appropriate because the Alien™ RX Micro Cannula device has the same fundamental scientific technology and intended use as the ERCP Cannula and is constructed of “similar” material used in the ERCP Cannula and other FDA “cleared” medical devices.

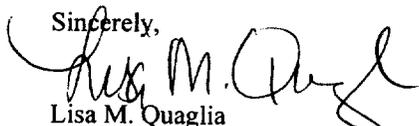
The terms “substantially equivalent,” “similar,” and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug, and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

Boston Scientific Corporation has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, Boston Scientific requests that the FDA keep and maintain confidential both the existence and the contents of the Premarket Notification in accordance with 21 CFR 807.95(b). Boston Scientific also request that the FDA keep and maintain confidential the contents of this letter.

If you have any questions about this notification, please contact me at:

Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
Tel: 508-650-8267
Fax: 508-650-8389

Sincerely,


Lisa M. Quaglia
Regulatory Affairs Manager

APR 3 9 39 AM '01
FDM/GDRH/OCE/DID

62

SK#9

CDRH SUBMISSION COVER SHEET

Date of Submission: April 2, 2001

FDA Document Number:

Section A

Type of Submission

<p>PMA</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p>PMA Supplement</p> <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<p>PDP</p> <input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<p>510(k)</p> <input type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<p>Meeting</p> <input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
<p>IDE</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>Humanitarian Device Exemption</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<p>Class II Exemption</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<p>Evaluation of Automatic Class III Designation</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<p>Other Submission</p> <p>Describe submission:</p>

Section B

Applicant or Sponsor

Company / Institution name: <i>Boston Scientific Corporation</i>		Establishment registration number: <i>9912058</i>	
Division name (if applicable): <i>Microvasive Endoscopy</i>		Phone number (include area code): <i>(508) 650-8267</i>	
Street address: <i>One Boston Scientific Place</i>		FAX number (include area code): <i>(508) 650-8389</i>	
City: <i>Natick</i>	State/Province: <i>MA</i>	Country: <i>USA</i>	
Contact name: <i>Lisa M. Quaglia</i>			
Contact title: <i>Regulatory Affairs Manager</i>		Contact e-mail address: <i>quaglia@bsci.com</i>	

Section C

Submission correspondent (if different from above)

Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State/Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	

Section D1

Reason for Submission - PMA, PDP or HDE

- | | | |
|--|---|---|
| <input type="checkbox"/> New device
<input type="checkbox"/> Withdrawal
<input type="checkbox"/> Additional or expanded indications
<input type="checkbox"/> Licensing agreement

<input type="checkbox"/> Process change:
<input type="checkbox"/> Manufacturing
<input type="checkbox"/> Sterilization
<input type="checkbox"/> Packaging
<input type="checkbox"/> Other (specify below)

<input type="checkbox"/> Response to FDA correspondence:
<input type="checkbox"/> Request for applicant hold
<input type="checkbox"/> Request for removal of applicant hold
<input type="checkbox"/> Request for extension
<input type="checkbox"/> Request to remove or add manufacturing site

<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in design, component, or specification:

<input type="checkbox"/> Software
<input type="checkbox"/> Color Additive
<input type="checkbox"/> Material
<input type="checkbox"/> Specifications
<input type="checkbox"/> Other (specify below)

<input type="checkbox"/> Labeling change:
<input type="checkbox"/> Indications
<input type="checkbox"/> Instructions
<input type="checkbox"/> Performance Characteristics
<input type="checkbox"/> Shelf life
<input type="checkbox"/> Trade name
<input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Location change:
<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Sterilizer
<input type="checkbox"/> Packager
<input type="checkbox"/> Distributor

<input type="checkbox"/> Report submission:
<input type="checkbox"/> Annual or periodic
<input type="checkbox"/> Post-approval study
<input type="checkbox"/> Adverse reaction
<input type="checkbox"/> Device defect
<input type="checkbox"/> Amendment

<input type="checkbox"/> Change in ownership
<input type="checkbox"/> Change in correspondent |
|--|---|---|

Section D2

Reason for Submission — IDE

- | | | |
|---|--|---|
| <input type="checkbox"/> New device
<input type="checkbox"/> Addition of institution
<input type="checkbox"/> Expansion / extension of study
<input type="checkbox"/> IRB certification
<input type="checkbox"/> Request hearing
<input type="checkbox"/> Request waiver
<input type="checkbox"/> Termination of study
<input type="checkbox"/> Withdrawal of application
<input type="checkbox"/> Unanticipated adverse effect
<input type="checkbox"/> Notification of emergency use
<input type="checkbox"/> Compassionate use request
<input type="checkbox"/> Treatment IDE
<input type="checkbox"/> Continuing availability request

<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in:
<input type="checkbox"/> Correspondent
<input type="checkbox"/> Design
<input type="checkbox"/> Informed consent
<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Manufacturing process
<input type="checkbox"/> Protocol - feasibility
<input type="checkbox"/> Protocol - other
<input type="checkbox"/> Sponsor

<input type="checkbox"/> Report submission:
<input type="checkbox"/> Current investigator
<input type="checkbox"/> Annual progress
<input type="checkbox"/> Site waiver limit reached
<input type="checkbox"/> Final | <input type="checkbox"/> Response to FDA letter concerning:
<input type="checkbox"/> Conditional approval
<input type="checkbox"/> Deemed approved
<input type="checkbox"/> Deficient final report
<input type="checkbox"/> Deficient progress report
<input type="checkbox"/> Deficient investigator report
<input type="checkbox"/> Disapproval
<input type="checkbox"/> Request extension of time to respond to FDA
<input type="checkbox"/> Request meeting |
|---|--|---|

Section D3

Reason for Submission - 510(k)

- | | | |
|--|---|--|
| <input type="checkbox"/> New device
<input type="checkbox"/> Additional or expanded indications
<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in technology
<input checked="" type="checkbox"/> Change in design | <input type="checkbox"/> Change in materials
<input type="checkbox"/> Change in manufacturing process |
|--|---|--|

Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1 KOG	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:		
510(k) Number	Trade or proprietary or model name	Manufacturer
1 K833417	1 Contour™ ERCP Cannula	1 Boston Scientific Corporation
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information --- Applicable to All Applications

Common or usual name or classification name: *Cannula*

Trade or proprietary or model name	Model number
1 Alien™ RX Micro Cannula	1 4530
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):					
1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory testing Animal trials Human trials

Section G Product Classification - Applicable to All Applications

Product code: KOG	C.F.R. Section: 876.1500	Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification panel: <i>Gastroenterology and Urology</i>		

Indications (from labeling):
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.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form. FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: <i>1828132</i>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name: <i>Boston Scientific Corporation</i>		Establishment registration number:	
Division name (if applicable): <i>Spencer Facility</i>		Phone number (include area code): <i>(508) 650-8267</i>	
Street address: <i>780 Brookside Drive</i>		FAX number (include area code): <i>(508) 650-8389</i>	
City: <i>Spencer</i>	State / Province: <i>IN</i>	Country: <i>USA</i>	
Contact name: <i>Lisa M. Quaglia</i>			
Contact title: <i>Regulatory Affairs Manager</i>		Contact e-mail address: <i>quaglia@bsci.com</i>	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: <i>(b) (4)</i>	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name: <i>(b) (4)</i>		Establishment registration number: <i>(b) (4)</i>	
Division name (if applicable):		Phone number (include area code): ()	
Street address: <i>(b) (4)</i>		FAX number (include area code): ()	
City: <i>(b) (4)</i>	State / Province: <i>(b) (4)</i>	Country: <i>(b) (4)</i>	
Contact name:			
Contact title:		Contact e-mail address:	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	

Boston Scientific Corporation / Microvative Endoscopy

Special 510(k): Device Modification

Alien™ RX Micro Cannula

April 2, 2001

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Section 1
DEVICE INFORMATION

Device Name

The device trade name and common/classification names are:

Device Trade Name	Common/Classification Name
Alien™ RX Micro Cannula	Cannula

Address and Registration #

The address and registration number of the manufacturer and sterilization site for the Alien™ RX Micro Cannula is:

Manufacturer	Sterilization Site
Boston Scientific Corporation 780 Brookside Drive Spencer, IN 47460 FDA Registration #: 1828132	Cosmed Of Rhode Island 8 Industrial Dr. Coventry, RI 02816 Registration # 1222273

Device Class

CFR Number: 21 CFR Part 876, Section 1500
Regulatory Class: Class II
Product Code: KOG

Device Panel – Gastroenterology and Urology

Predicate Device

The predicate device is the ERCP Cannula, 510(k) K833417, Substantial Equivalence Date: November 28, 1983.

Labeling

Draft Labels and Draft Device Drawing are included herein as Appendices A and B, respectively. There is no advertisement (i.e., brochures) at this time.

The label for the proposed device, the Alien™ RX, is derived from that of the currently marketed Rapid Exchange™ ERCP Cannula, cleared via 510(k) K970054. This device has the same Intended Use as the proposed device. The only changes to the Rapid Exchange™ ERCP Cannula label include a latex warning and device dimensional characteristic (i.e., outer diameter). Labels for the proposed device – the Alien™ RX Micro Cannula, the predicate device – the Contour™ ERCP Cannula, and the Rapid Exchange™ ERCP Cannula are included in Appendix A.

Instructions for Use

The Instructions for Use are modified slightly from those of the predicate device however, the technology and basic design are the same. The proposed device, the Alien™ RX, is designed to pass through the lumen of another device, such as a cannula or sphincterotome, which has been passed through an endoscope itself. The predicate device is designed to pass directly through the endoscope by itself. In addition, the outer diameter of the Alien™ RX catheter shaft is smaller than that of the predicate device and therefore, the cannula must be advanced in shorter movements to prevent damage to the device, such as kinking. Refer to Appendix C for Instructions for Use.

Intended Use

The Intended Use of the proposed Alien™ RX Micro Cannula is the same as that of the predicate device, the Contour™ ERCP Cannula.

The devices are 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.

As required, the Indications for Use Statement is included in Appendix D.

Section 2 DEVICE DESCRIPTION AND COMPARISON

Background

Boston Scientific currently markets the Contour™ ERCP Cannula that was cleared via 510(k) K833417. This product, specifically the “5-4-3” tip Contour™, is a single lumen ERCP cannula, with an outer diameter of 5 Fr that tapers over the distal 10mm from 5 Fr to 3 Fr. Its catheter shaft is constructed of tetrafluoroethylene (TFE) and is 210 cm in length. The tip is pre-curved and marked with both paint and radiopaque markers for visualization through the endoscope and during fluoroscopy, respectively.

Inside the catheter shaft is a stiffening stylet composed of stainless steel that is present to increase rigidity of the cannula during scope passage. When this stiffener is removed, a .018” guidewire can be placed, and contrast media may be injected through the cannula. The cannula has a T-fitting hub composed of ABS (Acrylonitrile Butadiene Styrene) that allows the physician access to one port for injection and another port for the guidewire, simultaneously.

The design of the proposed device, the Alien™ RX Micro Cannula, is based on that of the predicate device, the 5-4-3 Contour™ ERCP Cannula. In addition, the materials and labeling are “similar” to those used in the FDA cleared Microvasive® Endoscopy Microknife™, Sphincterotome, Microvasive® Urology Lumenator™ Injectable Guidewire, and the Microvasive® Rapid Exchange ERCP Cannula. In reviewing the design of the Alien™ RX versus that of the Contour™ ERCP Cannula while using the 510(k) “Substantial Equivalence” Decision-Making Process, as outlined in ODE Guidance Document No. K96-1, “Guidance on the CDRH Premarket Notification Review Program, it was determined that the technological characteristics, basic design, and intended use of the Alien™ RX Micro Cannula did not represent any significant changes. Therefore, a special 510(k) is appropriate.

Proposed Device

The proposed device, the Alien™RX Micro Cannula, is a single lumen cannula that measures 205cm in length and is consistently 3 French OD with a rounded distal tip. The components include the catheter shaft, hypotube, and luer assembly.

Catheter Sheath

The single lumen catheter sheath is made of PEEK 381 G colored black (used also in the Microknife sphincterotome). The diameter of the Alien™ RX catheter is designed so as to accommodate a .025” guidewire and pass through a .035” lumen. The length of the Alien™ RX is 205 cm., versus the Rapid Exchange™ devices that have a 200 cm. catheter. These additional 5 cm allow the micro cannula out of any RX c-channel or XL product.

Hypotube

The hollow hypotube is composed of 304 stainless steel and allows for injection of contrast media. It is 130 cm. with an outer diameter of .020” and an inner diameter of .017”. The material used in this hypotube is 304 stainless steel, which is identical to the material used in the stiffening stylet of the Contour™ ERCP Cannula.

Luer assembly

The luer assembly is composed of blue PVC with an adapter cap made of natural nylon zytel 101L and a gland assembly made of silicone and latex. Microvasive® Urology uses this same design in its Lumenator™ Injectable Guidewire.

Modifications to Predicate Device

The Alien™ RX Micro Cannula design includes the following modifications made to the predicate device, the single lumen 5-4-3 Contour™ ERCP Cannula.

Catheter

The proposed device, the Alien™ RX Micro Cannula, differs in design from the predicate device, the Contour™ ERCP Cannula, as its catheter sheath is 3 Fr throughout versus 5 Fr tapering to a 3 Fr tip. In addition, the working lengths between the two devices differ; the Alien™ RX is 205 cm whereas the Contour™ is 210 cm (note however that the Rapid Exchange™ devices have a catheter working length of only 200 cm.). The material of the catheter has changed; the Contour™ catheter is composed of TFE, whereas the Alien™ RX catheter is composed of PEEK (also used in the Microknife™ RX Sphincterotome cleared via 510(k) K973826).

In designing the Alien™ RX, several features have been eliminated from the Contour™ ERCP Cannula due to lack of necessity. The distal paint and radiopaque markers of the Contour™, along with the strain relief, are not present in the Alien™ RX. Paint markers are not needed on the Alien™ RX because it is designed to be placed through another device with its own markings that are used for visualization. Radiopaque markers, used to indicate position during fluoroscopy, are not needed on the Alien™ RX because the catheter is not designed to be viewed via x-ray imaging. Finally, a strain relief is not needed on the Alien™ RX because there is no bonded area between the luer assembly and the catheter.

Hypotube

The Contour™ ERCP Cannula has a solid stainless steel stiffener inside the cannula that aids in scope passage but must be removed before injecting through the cannula. The stiffener in the Alien™ RX is a stainless steel hollow hypotube that also aids in scope passage however, it need not be removed before injecting through the cannula.

Luer Assembly

Another modification to the Contour™ ERCP Cannula was the removal of the ABS T-fitting hub. This hub allowed the physician access to one port for injection and another port for the guidewire, simultaneously. This was not required for the Alien™ RX and a removable hub, specifically a PVC/Nylon/Silicone/Latex luer assembly (also used in the Lumenator™ Injectable Guidewire cleared via 510(k) K897152), was added for either guidewire insertion or for injection.

Table of Comparison

A description of the accumulated changes that have occurred to the ERCP Cannula since the clearance of 510(k) K833417 is presented in Table 1 on page 7. These changes have been incorporated into the proposed device, the Alien™ RX Micro Cannula.

Section 3
PURPOSE OF CURRENT SUBMISSION

The primary purpose of this Special 510(k) submission is to obtain clearance for a cannula, the Alien™ RX Micro Cannula, that is compatible with other Rapid Exchange™ devices and can accommodate a .025" guidewire.

Section 4 SUBSTANTIAL EQUIVALENCE

The modified ERCP Cannula, the Alien™ RX, has the following similarities to the predicate device cleared in 510(k) K833417.

- **Same** intended use
- **Same** indications for use
- **Same** technology, similar operating principle
 - The proposed device, the Alien™ RX, is designed to pass through the lumen of a device, such as a cannula or sphincterotome that has been passed through an endoscope itself. The predicate device is designed to pass directly through the endoscope. The outer diameter of the predicate device's catheter shaft is smaller than that of the predicate device and therefore, the cannula must be advanced in shorter movements to prevent damage to the device, such as kinking.
- **Same** basic design
 - catheter shaft
 - stainless steel stiffener
 - luer assembly
- **Same** type sterilization
 - Ethylene Oxide (EtO)

A claim of substantial equivalence with the legally marketed predicate device is based upon the substantial similarities. A tabular comparison is provided on the following page in Table 1.

TABLE I COMPARISON OF CONTOUR™ ERCP CANNULA TO ALIEN™RX MICRO CANNULA		
Note: All dimensions are nominal	Alien™ RX Micro Cannula (This 510(k))	Contour™ 5-4-3 Tip ERCP Cannula K833417 (ERCP Cannula)
USE		
Indication	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.	
Route of Administration	Endoscopic	Endoscopic
SHAFT		
Usable Length	205 cm	210 cm
Proximal Shaft OD	3 Fr	3 Fr
Distal Shaft OD	3 Fr	5 Fr
Distal Taper Length	N/A	10 mm
Tip	Buffed	Die
Lumens	1	1
Catheter Shape	Straight	Pre-curved, heat set
Open Guidewire Channel	No	No
Recommended Guidewire Size	0.025"	0.018"
Radiopaque Marker	No	Yes – Tantalum
Paint Marker	No	Yes – TFE paint
Strain Relief	No	Yes – Polyolefin
STIFFENER		
Stiffener	Yes- hypotube	Yes- stylet
HUB		
Hub shape	Locking hub/luer assembly	T-fitting
MATERIALS		
Shaft	Peek 381 G	Teflon®
Hypotube	304 Stainless Steel	304 Stainless Steel
Luer assembly	Blue PVC, nylon, silicone, latex	Polyolefin

In summary, the proposed Alien™ RX Micro Cannula described in this submission is, in Boston Scientific Corporation / Microvase Endoscopy's opinion, substantially equivalent to the predicate device, the Contour™ ERCP Cannula, cleared via K833417 (ERCP Cannula).

Section 5 SUMMARY OF DESIGN CONTROL ACTIVITIES

Overview

The proposed device, the Alien™ RX Micro Cannula, will be manufactured at the Boston Scientific facility in Spencer, IN, which follows the current design control protocol discussed in this overview.

For each project, the Core Team (led by a Core Team leader, and including members from appropriate groups within the organization) completes five phases of design development: Proposal, Definition, Development, Validation, and Commercialization. At the end of each phase a formal review is performed by the Project Investment Board (PIB) to assess that the project requirements are met, to decide on the project continuation or early termination, and to assess appropriate deviations from the development procedures. Design outputs are defined and documented in product specifications. The design is verified by various validations to demonstrate that design outputs meet inputs and that the device is safe and effective for its intended use. Successful design-transfer-to-production specifications are demonstrated through process and product validation.

Once the design is qualified through design verification, processes are developed, validated for normal and worst case conditions and qualified by testing the final manufactured product.

Final manufactured products are manufactured in accordance with routers specifying sequence of work operations and the documentation is connected to those operations. Detailed written procedures exist to describe all manufacturing processes.

Design development and control records are located in the Project File, which functions as the Design History File. The Project File contains or references all records necessary to demonstrate that the design and manufacture were developed in accordance with the approved design plan and the requirements of ISO 9001 / EN 46001 / MDD. The Design History Files are maintained by the Quality Engineer at the manufacturing facility.

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015
Special Notice
Alien™ RX Micro Cannula
April 2, 2001

Boston Scientific Corporation
One Boston Scientific Place
Marlborough, MA 01760

Risk Analysis: FMEA and Bench Testing

(b) (4)



Section 6
BIOCOMPATIBILITY

(b) (4)



Section 7
STERILIZATION, PACKAGING, PYROGENICITY

Sterilization

In accordance with a memo addressed by Robert Sheridan to the ODE Review Staff on 510(k) Sterility Review Guidance [510(k) Memorandum #K90-1, 2/12/90], the following information is included, concerning the methods of sterilization and identification of packaging materials.

Boston Scientific Corporation will utilize ethylene oxide (EtO) gas to sterilize the Alien™ RX Micro Cannula. This method is currently used for the predicate device, the Contour™ ERCP Cannula (510(k) K833417), as well as the Microknife™ Sphincterotome (510(k) K973826), the Lumenator™ Injectable Guidewire (510(k) K897152), and the Microvasive® Rapid Exchange ERCP Cannula (510(k) K970054). Sterilization is performed by outside firms per contractually established guidelines. Sterilization validation is accomplished using a protocol consistent with the overkill approach described in the Association for the Advancement of Medical Instrumentation March 31, 1988, "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices." The sterility assurance level (SAL) for the Alien™ RX is 1×10^{-6} . To substantiate this SAL, Boston Scientific performs sterility testing on actual product, as well as on fractional-exposed products challenged with *Bacillus subtilis* var. niger. For routine sterilization, batches are released on sterility testing of systems challenged with 1×10^6 *Bacillus subtilis* var. niger. For release purposes, maximum residue levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol are at or below the levels for "devices contacting mucosa," as described in the proposed rule on ETO residuals (June 23, 1978, Federal Register):

Ethylene Oxide:	250 ppm
Ethylene Glycol:	5000 ppm
Ethylene Chlorohydrin:	250 ppm

Packaging

The proposed device, the Alien™ RX Micro Cannula will be loaded into a guidewire hoop and packaged in a Tyvek Pouch that will be sealed with a pouch sealer. It will be sterilized in the pouch. This guidewire hoop and pouch are also used in the packaging of the currently marketed Nasobiliary Catheters (510(k) K982508).

Pyrogenicity

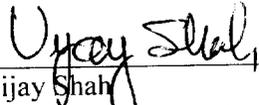
Bacterial endotoxins will be monitored for this product family on a routine basis using the Limulus Amebocyte Lysate (LAL) assay as described in the "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices," issued by the FDA in December 1987 and in USP, Chapter 85, "Bacterial Endotoxins Test." The Alien™RX will be released for shipment only if the endotoxin level is less than 0.5 EU/ml (endotoxin units). The sensitivity of the pyrogen assay is 0.25 EU/ml.

Section 8
DECLARATION OF CONFORMITY

Declaration of Conformity with Design Controls

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

The manufacturing facility, Boston Scientific Corporation, Spencer, Indiana, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



Vijay Shah
Quality Assurance Manager
Boston Scientific Corporation / Microvative Endoscopy

4/02/01

Date

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.

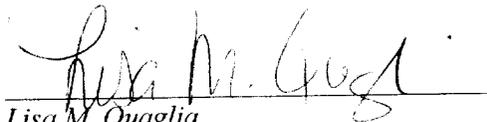
COMPARISON OF CHARACTERISTICS: The proposed device is substantially equivalent to currently marketed devices used for cannulation and injection of contrast media into the biliary and pancreatic ductal systems.

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

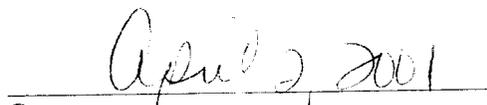
Section 10
TRUTHFUL AND ACCURATE STATEMENT

Premarket Notification
Truthful and Accurate Statement
As Required by 21 CFR 807.87(k)

I certify that based upon the data and information submitted to me in the course of my responsibilities as Manager of Microvasive Endoscopy Regulatory Affairs employed by Boston Scientific Corporation / Microvasive Endoscopy Division, that data and information submitted in this Premarket notification are, to the best of my knowledge, truthful and accurate and that no material facts have been omitted.



Lisa M. Quaglia
Regulatory Affairs Manager
Boston Scientific Corporation



Date

APPENDIX A: Labels

Appendix A-1: Alien™ RX Micro Cannula Label
Proposed Device

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2014

Special 510(k) Premarket Notification
Alien™ RX
April 2, 2001

APRV:
DRAWN BY: *[Signature]*
CHECK: *[Signature]*
03/27/01



DA TA B ASE:
UPN: M0054530ME10
EVALUATION ONLY

TITLE: ALIEN™ RX Micro Cannula
LABEL BLANK: 435630-01

971

551971-01
REV. 01

TEST000
2002-03

ALIEN™ RX
3 FR Micro Cannula
MARKET EVALUATION ONLY
UPN#: M005 4530ME10

TEST000
2002-03

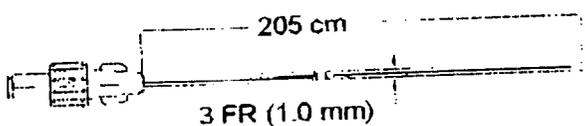
ALIEN™ RX
3 FR Micro Cannula
MARKET EVALUATION ONLY
UPN#: M005 4530ME10

TEST000
2002-03

ALIEN™ RX
3 FR Micro Cannula
MARKET EVALUATION ONLY
UPN#: M005 4530ME10

435630-01 REV. B

ALIEN™ RX Micro Cannula 3 FR (1.0 mm)



Do not use if the cannula is damaged or if the cannula is not marked with the following information: Length, Manufacturer, Lot Number, and Expiration Date.	Do not use if the cannula is not marked with the following information: Lot Number, Expiration Date, and Manufacturer.
.025 in. (.63 mm)	

CAUTION:
This product contains natural rubber latex which may cause allergic reactions in some individuals.

REF/Catalog No.: **4530ME1**
カタログ番号 **M0054530ME10**
UPN:

LOT No.: ロット番号 TEST000	Use Before 使用期限 2002-03
--	--------------------------------------

Single use Only 使用は1回限り
再使用しないこと

STERILE EO エチレンオキサイドガスで
滅菌済

See Instructions For Use
取扱説明書を参照して下さい

For U.S.A. Only;
Caution: Federal Law (USA) restricts this device to sale,
distribution, and use by or on the order of a physician.

MARKET EVALUATION ONLY



DCO History:	DCO	Rev.	Date	Description
	125159	01	03/27/01	Create new Market Evaluation label spec

FOR REFERENCE ONLY
MAR 29 2001
BSC SPENCER (NOT FOR MFRG)
Boston Scientific - Spencer
Label Specification
ALIEN™ RX Micro Cannula
Label Spec. No.: 551971-01 Rev.: 01
Sheet 1 of 1

FORMAT: 551971-01
NOTES: The expiration date for this product is to be the 12th month (1 year) from the date the labels are printed.
FORMAT: YYYY-MM

Appendix A-2: Rapid Exchange™ ERCP Cannula Label
Predicate Label

Appendix A-3: Contour™ ERCP Cannula Label
Predicate Device

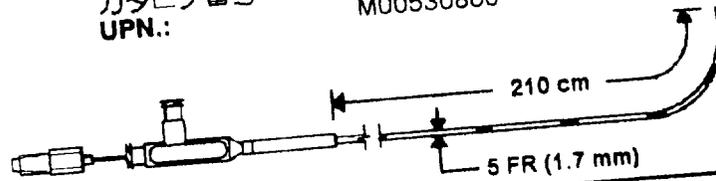


(1) CONTOUR™ ERCP CANNULA

ERCP-CANULE -- 5-4-3 TIP
CANULE CPRE -- EXTREMITÉ 5-4-3
ERCP-KANÜLE -- 5-4-3-SPITZE
ΣΩΛΗΝΙΑΣ ERCP -- ΑΚΡΟ 5-4-3
CANNULA PER ERCP -- PUNTA 5-4-3
CÁNULA PARA ERCP -- PUNTA 5-4-3
CÁNULA PARA CPER -- PUNTA 5-4-3
ERCP-KANYL -- 5-4-3-SPETS
ERCP KANYLE -- 5-4-3 SPIDS
ERCP カニューレ -- 5-4-3 チップ

5-4-3 TIP

REF/ Catalog No.: **3088**
カタログ番号
UPN.: M00530880



Recommended Guidewire

Aanbevolen voerdraad	Fio-gula
Guides recommand	Gu'a recomandada
Empfohlener Führungsdraht	Rekommenderad ledare
Κοινό Πύργος	Anbefalet guidewire
Guida raccomandata	シヨートノーズ

.018 in. (.46 mm)

LOT NO.:
ロット番号 **522099C**

USE BEFORE:
使用期限
10/2001

ⓧ SINGLE USE ONLY
使用は1回限り
再使用しないこと

STERILE EO
エチレンオキサイドガスで
滅菌済

⚠ See Instructions for Use.
取扱説明書を参照して下さい

For USA only:
Caution: Federal law (U.S.A.) restricts this device to sale, distribution,
and use by or on the order of a physician.



717816-09 Rev. C

MADE IN U.S.A.

160-03964-08 Rev. A

36

APPENDIX B: Draft Engineering Drawing

Appendix B-1: Alien™ RX Micro Cannula Drawing **Proposed Device**

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Appendix B-2: Contour™ ERCP Cannula Drawing
Predicate Device

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Special 510(k) Premarket Notification
Alien™ RX Micro Cannula
March 30, 2001

Boston Scientific Corporation
One Boston Scientific Place
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APPENDIX C: Draft Instructions for Use
Proposed Device, Alien™ RX Micro Cannula

INSTRUCTIONS FOR USE

CAUTION: This product contains natural rubber latex, which may cause allergic reactions.

WARNING: For single use only. **DO NOT REUSE, REPROCESS OR RESTERILIZE.** Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DESCRIPTION

The Alien™ RX Micro Cannula is a single lumen 3 Fr ERCP cannula capable of being passed through a .035" guidewire lumen. The Alien™ RX Micro Cannula is then capable of accepting a .025" Jagwire™ or smaller in diameter guidewire for intervention. A proximal luer connection will include a stiffening hypotube for injection capabilities and to aid in scope passage. The Alien™ RX Micro Cannula may be placed with or without the aid of a guidewire.

Catheter Shaft:

The Alien™ RX Micro Cannula accommodates .025" Jagwire™ or smaller diameter guidewires. Contrast medium injection may be achieved through the proximal luer and through the hypotube stiffening stylet. The Alien™ RX Micro Cannula is 205 cm in length.

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. The contrast medium is injected through the cannula and fluoroscopy or x-ray is performed to obtain the cholangiogram.

CONTRAINDICATIONS

Contraindications for this device are those specific to endoscopic retrograde cholangiopancreatography (ERCP).

POSSIBLE COMPLICATIONS

Possible complications include, but may not be limited to:

- Perforation
- Hemorrhage
- Hematoma
- Septicemia/Infection
- Cholangitis
- Pancreatitis
- Allergic reaction to contrast medium

PRECAUTIONS

The Alien™ RX Micro Cannula should only be used by or under the supervision of physicians trained in ERCP. A thorough understanding of the technical principles, clinical applications and risks associated with ERCP is necessary before using this device.

Monitor the cannula position with contrast medium injection and fluoroscopy. The Alien™ RX Micro Cannula is designed for use with an ERCP catheters that have an .035" guidewire lumen.

The Alien™ RX Micro Cannula is recommended for use with the Microvasive® Jagwire™ .025", Glidewire® .020" or Pathfinder® .018" Guidewires.

Any use of this device, other than those indicated in these instructions, is not recommended.

Caution: This product contains natural rubber latex, which may cause allergic reactions.

PREPARATION

The Alien™ RX Micro Cannula is supplied sterile. Carefully examine the unit to verify that neither the contents or the sterile package has been damaged in shipment. **DO NOT USE** if damaged. Immediately return damaged product to Microvasive®.

1. Open the package by pulling apart the top two edges of the pouch located above the product label to break the seal.
2. Remove the Alien™ RX Micro cannula from the hoop by holding on to the catheter itself, not the luer hub.
3. Inspect the Alien™ RX Micro Cannula for any visual damage, such as kinks.
4. Prior to clinical use, test the cannula by flushing it with sterile water or saline.

Precaution: kinks in the cannula will hinder injection capability and guidewire passage. Do not use if any defect is found during inspection. Please notify and return for replacement.

5. Fill a 10 ml or larger syringe with contrast medium and flush the cannula to remove all the air.
6. The Alien™ RX Micro Cannula is now ready to use.

DIRECTIONS FOR USE

Precaution: The Alien™ RX Micro Cannula should be advanced using short, deliberate 2-3 cm movements to prevent inadvertent damage to the device. The Alien™ RX Micro Cannula is designed to pass through a .035" lumen of an existing .035" Rapid Exchange Cannula or Cannulating Sphincterotome.

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1. Attach the Microvasive® Rapid Exchange Locking Device to the endoscope ensuring the locking feature appears just above the grommet.
2. Insert a Rapid Exchange cannula or cannulating sphincterotome for initial cannulation. The Alien™ RX Micro Cannula may then be inserted through the guidewire channel of the Rapid Exchange Cannulating device.
3. Once the Alien™ RX Micro Cannula tip is extended out the distal tip of the cannulating device, the device may be utilized for cannulation. If a guidewire is desired, remove the stiffening hypotube and insert the guidewire into the proximal end of the Alien™ RX Micro Cannula and advance through the cannula.
4. After the guidewire is in its desired location, advance the Alien™ RX Micro Cannula and initial cannulating device. For contrast injection, remove the guidewire, reinsert the stiffening hypotube and inject. If you are using the Rapid Exchange XL cannula or cannulating sphincterotome you may inject through its injection lumen, however the contrast will not exit through the tip of the Alien™. It will exit the Rapid Exchange catheter. Reinsert the guidewire for further manipulation if necessary.
5. Once the initial cannulating device is secure in the desired location, remove the Alien™ RX Micro Cannula and guidewire.

DEVICE REMOVAL

The Alien™ RX Micro Cannula should be removed with the compatible .025" or smaller diameter guidewire.

1. Upon securing the Rapid Exchange Cannula or Cannulating Sphincterotome in the desired location, retract the Alien™ RX Micro Cannula and guidewire simultaneously.
2. Once the devices have been removed from the partially enclosed guidewire channel, an .035" Jagwire™ may be inserted.

HOW SUPPLIED

The device is supplied sterile by ethylene oxide gas and is intended for single patient use only. **DO NOT REUSE, REPROCESS OR RESTERILIZE.**

STORAGE

Store at controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of this instrument as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such instruments.

Prices, models and availability are subject to change without notice.

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Glidewire® is a registered trademark of Terumo Corporation.

Alien™ and Jagwire™ are trademarks of Boston Scientific.

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APPENDIX D: Indications for Use Statement

Proposed Device, Alien™ RX Micro Cannula

Indications for Use Statement

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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 _____
(Per 21 CFR 801.109)

OR

Over the Counter Use _____