

MAY 13 2007

K01149

page 1 of 2

SMDA 510(k) SUMMARY

DISPOSABLE BENDING CANNULA PR-233Q

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-Shinjuku, Shinjuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: Of R&D Division, Endoscope Group	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81- 426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name:	Laura Storms-Tyler
Address, Phone and Fax Numbers:	Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	Disposable Bending Cannula PR-233Q
Common Name:	Disposable Cannula
Classification:	21 CFR 876.1500 Endoscope and accessories 21 CFR 876.5010 Biliary catheter and accessories
Predicate Device:	PR-23Q DISPOSABLE BALL TIP CANNULA K950729 KD-6G WIRE GUIDED PAPILOTOMY KNIVES K950166

15 011149

page 2 of 2

D. Description of the Device(s)

The subject device is a cannula which has a bending function (angle wire), to be used in accordance with Intended Use of the Device. This bending function enables the subject device to be manipulated in 2 directions and leads to easier insertion into the biliary and pancreatic ducts.

E. Intended Use of the Device(s)

The subject device, DISPOSABLE BENDING CANNULA PR-233Q has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, this subject device Disposable bending cannula PR-233Q does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.



MAY 15 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Optical Co., LTD
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K011149
DISPOSABLE BENDING CANNULA PR-233Q
Dated: March 19, 2001
Received: April 16, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG
21 CFR §876.5010/Procode: 78 FGE

Dear Ms. Storms-Tyler:

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,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number(if known): Not assigned yet K011149
Device Name: DISPOSABLE BENDING CANNULA PR-233Q

Indications for Use:

This instrument has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

(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)

(Optional Format 1-2-96)

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices



MAY 15 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Optical Co., LTD
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

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Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number(if known): Not assigned yet K011149
Device Name: DISPOSABLE BENDING CANNULA PR-233Q

Indications for Use:

This instrument has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

(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)

(Optional Format 1-2-96)

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

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Memorandum

From: Reviewer(s) - Name(s) M. J. Cornelius

Subject: 510(k) Number K011149

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 N/A

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- 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):

K09 - 876.1500 II - 78
FGE 876.5010 II - 18

Review: James H. Harris ULDB
(Branch Chief) (Branch Code)

5-14-01
(Date)

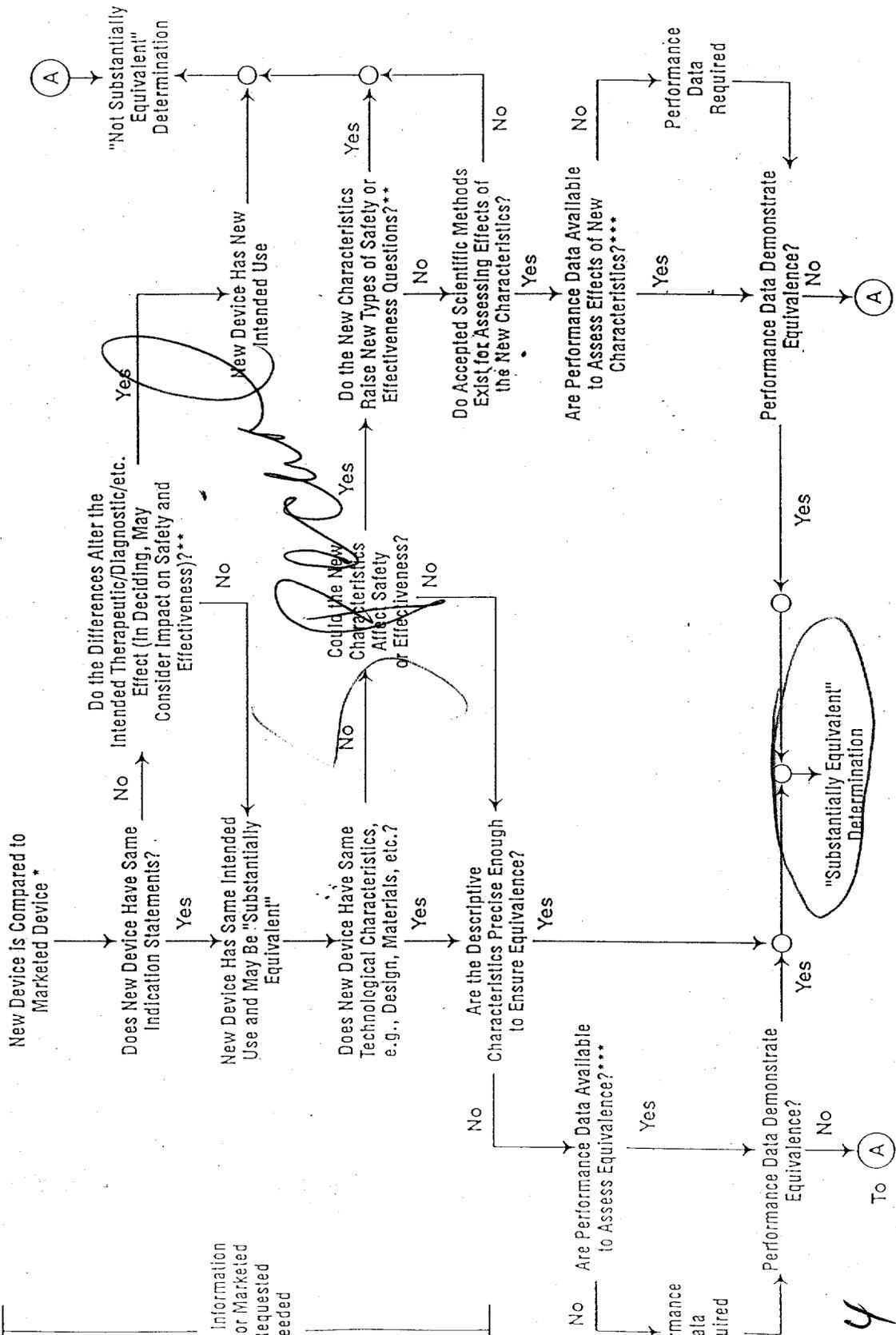
Final Review: David G. Slegman
(Division Director)

5/15
(Date)

(JME)

Revised: 8/17/99

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



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

** This Decision is Normally Based on Descriptive Information Alone, But Limited Text Information is Sometimes Required.
 *** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

4 To A

To: THE FILE **RE:** DOCUMENT NUMBER: K011149 Disposable Bending ERCP 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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. 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.
2. 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 the addition of a bend in the guide wire to angle the cannula tip, while the predicate devices (PR-23Q Disposable ball tip cannula K950729) and (KD-6 wire guided papillotmy Knives K950166) have the identical guide wire but without the angle. Labeling modified to addressing the use of the angel wire tip: a warning has been added which cautions the user not to insert the cannula too deeply to into the pancreatic.
3. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics. (Section H)
4. **Design Control Activities Summary** which includes: (Section I)
 - 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) 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. (Attachment 3)
5. **Truthful and Accurate Statement**, (Attachment 5) a **510(k) Summary** (Attachment 4) and the **Indications for Use Enclosure**. (Attachment 2)

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 modification(s) 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.

Mary J. Cornelius

(Reviewer's Signature)

Comments

5/9/01
(Date)

revised:3/27/98

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Screening Checklist

For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: <i>PR-238 Disposable Bending Cannula</i>						<i>K₁₀</i>						
Submitter (Company):												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING	
						YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:												
a) "Special 510(k): Device Modification"						✓						
b) "Abbreviated 510(k)"								GO TO # 2,4,5				
c) Traditional 510(k)										GO TO #2, 5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS												✓ IF ITEM IS NEEDED
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class						✓						
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA						
d) compliance with Section 514 - performance standards						NA						
e) address of manufacturer						✓						
f) Truthful and Accurate Statement						✓						
g) Indications for Use enclosure						✓						
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)						✓						
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)						✓						
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals						✓						
k) Proposed Labeling:						✓						
i) package labeling (user info)												
ii) statement of intended use												
iii) advertisements or promotional materials												
i) MRI compatibility (if claimed)												
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:						✓						
i) Labeling												
ii) intended use												
iii) physical characteristics												
iv) anatomical sites of use												
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification						N/A						
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device						✓						
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS						✓						* If no - STOP not a special

6

LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*	✓			* If no - STOP not a special
d) Design Control Activities Summary	✓			
i) 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				
ii) 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				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) 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	✓			
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.	✓			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
	4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE						
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type		✓					
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.		✓					
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:		✓					
i) An identification of the applicable recognized consensus standards that were met		✓					
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below		✓					
iii) An identification, for each consensus standard, of		✓					

any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed	✓		
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device	✓		
v) A specification of any deviations from each applicable standard that were applied	✓		
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference	✓		
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations	✓		
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards	✓		

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 4/17/01

Reviewer: M. J. Cornelius
 Concurrence by Review Branch: [Signature]

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

10

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

**DRAERD REVIEWER RECORD FOR ORIGINAL 510(K)S,
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 16, 2001

THE OLYMPUS OPTICAL CO.
C/O OLYMPUS AMERICA, INC.
ENDOSCOPE DIVISION
TWO CORPORATE CENTER DRIVE
MELVILLE, NY 11747
ATTN: LAURA STOMS-TYLER

510(k) Number: K011149
Received: 16-APR-2001
Product: DISPOSABLE BENDING
CANNULA PR-233Q

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

K011149

OLYMPUS

March 19, 2001

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

Ref: Special 510(k) - Device Modification
K950729, PR-23Q Disposable Ball Tip Cannula, 3/17/95

RECEIVED

APR 16 10 17 AM '01

FDA/CDRH/OCE/DMC

Dear Sir / Madam:

Olympus Optical Co., LTD hereby submits this Special 510(k) : Device Modification to request a modification of our PR-23Q Disposable Ball Tip Cannula(#K950729). The modifications to this device is to provide an operating principle for bending the cannula tip that allows the user the ability to insert the cannula into the papilla and the left hepatic duct easier.

The modifications made to the subject device do not effect the intended use of the device or alter the fundamental scientific technology of the device.

Olympus America Inc(OAI) is submitting the pre-market notification on behalf of Olympus Optical Co, Ltd. However, for any questions, additional information, or future correspondence pertaining to this submission please contact Olympus America Inc. (OAI) as indicated.

I can be contacted by telephone at (631)844-5688, by facsimile at (631)844-5416 or 5554 and by e-mail at Laura.Storms-Tyler@olympus.com

Sincerely,

Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance

SK11
/

GM
H

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

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- 3. Declaration of Conformity with Design Controls
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Trade Name : DISPOSABLE BENDING CANNULA PR-233Q
 Common Name: Disposable Cannula

B. Class, Classification Number and Classification Name

21 CFR 876.1500 Endoscope and accessories, Class II *K09*
 21 CFR 876.5010 Biliary catheter and accessories, Class II *F9E*

C. Address and Registration

Applicant: Olympus Optical Co., LTD.
 2-3-1 Shinjuku Monolis Nishi-Shinjuku
 Shinjuku-ku, Tokyo Japan, 163-0914

Registration No; 8010047

Initial Importer: Olympus America Inc.
 Two Corporate Center Drive
 Melville NY 11747-3157

Registration No 2429304

Contact Person: Laura Storms-Tyler
 Director, Regulatory Affairs
 Olympus America Inc.
 Two Corporate Center Drive
 Melville NY 11747-3157
 Telephone (631)844-5688

D Performance Standards

None established under Section 514

E Predicate Device Information

The subject device is substantially equivalent to the following commercialized Olympus devices;

Subject Device	Substantially Equivalent Predicate Device	Corresponding 510(k) Notification	Concurrence Date
PR-233Q	PR-23Q DISPOSABLE BALL TIP CANNULA	K950729	3/17/95
	KD-6G WIRE GUIDED PAPILOTOMY KNIVES	K950166	2/22/95

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F. Labeling and Intended Use

Labeling

The following labeling materials for the subject devices are found in Attachment 1:

•Operation Manual

The operation manual for the subject device is basically the same the predicate device Except for the instructions for use of the angle wire. The labeling sections, which contain warnings and instructions for the angle wire, are highlighted.

Additionally, the labeling for the subject device contains a warning to the user prohibiting use of the device for deep insertion into the pancreatic duct. The predicate device did not contain this warning.

•Promotional materials

The following sentence is the main point we would like to claim.

It is easier to insert cannula into the papilla and the hepatic duct.

Intended Use

The subject device, DISPOSABLE BENDING CANNULA PR-233Q has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for deep insertion into the pancreatic duct.

The subject device labeling cautions the user not to deeply insert the cannula into the pancreatic duct.

The predicate device did not contain this warning.

This is the same intended use as previously cleared for the DISPOSABLE BALL TIP CANNULA PR-23Q.

G. Device Description and Comparison

1) Device Description

Following is comparison table between the subject device PR-233Q and predicate devices.

Specifications		Subject Device PR-233Q	Predicate Device PR-23Q(#K950729)	Predicate Device KD-6G(#K950166)
Working length (mm)		1950	1950	1950
Maximum insertion portion diameter (mm)		2.95	1.9	2.05
Lumen structure	Contrast medium lumen combining guide wire lumen:	Equipped	Equipped	Equipped
	Angle wire lumen	Equipped	Not equipped	Not equipped
	Knife wire lumen	Not equipped	Not equipped	Equipped
Applicable guide wire diameter (inch)		0.035	0.035	0.035
Markings on the cannula tip		Blue and Green	Black	Red and Black
Tip bending function(angle wire)		Provided	Not available	Not available
Fluoro tip		Provided	Provided	Provided
Reusable / Disposable		ETO Sterilized Disposable	ETO Sterilized Disposable	ETO Sterilized Disposable

<modified specification >

Markings on the cannula tip:

The patient contacting materials of the subject devices are identical to the material composition of the legally marketed predicate device, the WIRE GUIDED PAPILOTOMY KNIVES KD-6G(#K950166), except for the markers on the distal end of the tube, which had already been confirmed on their biological compatibility.

Tip bending function(angle wire):

The most significant change for the subject device is the addition of angle wire to bend the cannula tip.

2) Sterility Characteristics

•Sterility Assurance Level is the same as predicate device PR-23Q.

- 1.Method of sterilization : 20% Ethylene Oxide / 80% CO₂
- 2.Sterility Assurance Level : 10⁻⁶
- 3.Validation Method : AAMI Overkill Method
- 4.Ethylene Oxide Residuals : ETO - < 250 ppm
EC - < 250 ppm
EG - < 5000 ppm
- 5.Packaging : Film : Double layer
Polyethylene and polyethylene terephthalate
Sheet : Double layer
High density polyethylene coated with polyethylene (tyvek)
- 6.Pyrogenicity : We do not claim that the device is pyrogen free.

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H Substantial Equivalence

The subject device, DISPOSABLE BENDING CANNULA PR-233Q has the following similarities to the predicate devices which have received 510(k) concurrence.

- The same intended use
- The same operating principle
- The same SAL Value (10^{-6})
- The same material except for the marker on the distal end of the tube

In summary, the subject device, DISPOSABLE BENDING CANNULA PR-233Q described in this submission is in our opinion, substantially equivalent to the predicate devices

I Design Control Activities

The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO14971-1. The design verification tests that were performed as a result of this risk analysis assessment are listed below.

Refer to Attachment 3 for the Declaration of conformity with design controls.

Modification	Test performed	Acceptance Criteria
Tip Bending Function (Angle wire)	Bending testing of the angle for the operation of the handle (pull / push).	• Both angle pull and push complied with established in-house standards.
	• Durability	• Enough durability against repetitious bending device complied with established in-house standard.

The design validation indicated that there is potential for the angle wire to break and protrude out of the cannula under certain conditions. As an outcome of this finding, we have added specific warning to the instruction manual to advise users of this potential situation.

J. 510(k) Summary

Refer to Attachment 4 for the 510(k) Summary for DISPOSABLE BENDING CANNULA PR-233Q.

K Truthful and Accurate Statement

Refer to Attachment 5 for the Truthful and Accurate Statement of DISPOSABLE BENDING CANNULA PR-233Q

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Attachment 1

Draft Labeling and Promotional Materials

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DISPOSABLE BENDING CANNULA

PR-233Q



OLYMPUS ENDO-THERAPY

1 Symbols

The meaning(s) of the symbol(s) shown on the package and/or this instrument are as follows:

-  Refer to instructions.
-  Do not reuse.
-  Use by
-  Sterilized using ethylene oxide
-  Sterilization lot number
-  Lot number
-  Compatible with \varnothing 0.89 mm (0.035 inch) guidewire

2 Intended use

This instrument has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct. Do not use this instrument for any purpose other than its intended use.

3 Instruction manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed.

If you have any questions or comments about any information in this manual, please contact Olympus.

4 User qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

5 Signal words

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

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6 Nomenclature and functions

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Slider

The instrument's distal end bends when the slider is operated.

Model reference label

Sealing assembly

Branch

Handle

Insertion portion/
working length

Distal end

Tube

Luer adapter 2

This adapter is attached to the luer fitting.

Injection port

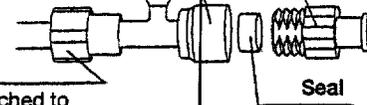
Attach a syringe here to inject a contrast medium.

Luer adapter 1

This adapter is attached to the branch.

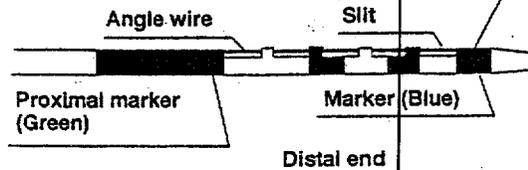
Luer fitting

A guidewire is passed through this opening. Turn clockwise to seal. Turn counterclockwise to loosen.



Sealing assembly

Fluoro tip



Proximal marker
(Green)

Marker (Blue)

Distal end

*Markers assist in positioning the distal end of the instrument and determining distance in the endoscopic field.

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7 Specifications

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WARNING

Use this instrument only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient or operator injury, malfunction or equipment damage may result.

Operating environment

Ambient temperature: 10 – 40°C (50 – 104°F), Relative humidity: 30 – 85%
Air pressure: 700 – 1060 hPa (0.7 – 1.1 kgf/cm²) (10.2 – 15.4 psia)

Specifications

Model	PR-233Q	
Distal end diameter	4 Fr	
Maximum insertion portion diameter (mm)	ø 2.95	
Working length (mm)	1950	
Applicable guidewire diameter (mm/inch)	ø 0.89/0.035	
Maximum angulation range	 90° (with slider pulled) 30° (with slider pushed)	
Compatible Olympus endoscopes (All of these parameters should be met.)	Length and model	Working length less than 1400 mm; JF, TJF
	Channel inner diameter (mm) (Color code)	ø 3.2 (Yellow) ø 4.2 (Orange) ø 5.5 (Pink)
	Other	With fluoro tip
Medical Device Directive		This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I sterile

NOTE

Maximum distal end angulation may vary depending on the condition of use such as the shape of the insertion portion of the endoscope and so on.

8 Storage

WARNING

Do not store the sterile package containing the instrument in places where it will be damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk or cause tissue irritation.

Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store it in direct sunlight.

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WARNING

- Do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue irritation.
- Before use, prepare and inspect the instrument as instructed below. Should the slightest irregularity be suspected, do not use the instrument; use a spare instead. Damage or irregularity may compromise patient or user safety, such as infection control risk, tissue irritation, punctures, hemorrhages or mucous membrane damage and may result in more severe equipment damage.

CAUTION

Do not coil the insertion portion with a diameter of less than 15 cm. This could damage the insertion portion.

9.1 Preparation **Spare Instrument**

Always have a spare instrument available.

9.2 Inspection

Wear appropriate personal protective equipment in accordance with their respective instruction manuals.

 Inspection of the sterile package**WARNING**

Do not attempt to sterilize the instrument. This could pose an infection control risk or cause equipment damage, and could not keep the function.

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Do not use the instrument.

 Inspection of operation**WARNING**

Do not bend the distal end more than 90 degrees. It could break and not bend smoothly (see Figure 1). Never use a broken product. When the yielded cannula is bent repeatedly, the angle wire may be cut and may stick out of the slit (see Figure 2). This could cause patient injury, such as perforations, hemorrhages or mucous membrane damage. Carry out open surgery or other possible treatment.

CAUTION

Do not use excessive force to bend the distal end. This could damage the instrument.

1. Straighten the insertion portion of the instrument and curve the distal end in the direction of the slit with your fingers when necessary.

NOTE

If the distal end is pre-curved too tightly, it will be difficult to bend in the opposite direction of the slit.

2. Hold the distal end and handle of the instrument. Push and pull the slider to confirm that the distal end bends smoothly in both the direction of the slit and the opposite direction.
3. Release the slider and confirm that the distal end straightens out.

9.3 Operation

WARNING

- Do not use for deep insertion in the pancreatic duct. The slits of the cannula may damage the pancreas and may cause serious pancreatic diseases.
- When using the instrument, always wear appropriate personal protective equipment. Otherwise, blood, mucous and other potentially infectious material from the patient could pose an infection control risk.
- Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view or in X-ray images, do not use it. This could cause patient injury, such as punctures, hemorrhages, or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not move the slider abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and/or instrument.
- Do not angulate the bending section of the endoscope or operate the forceps elevator abruptly while the distal end of the insertion portion is extended from the distal end of the endoscope. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not excessively bend the distal end. This could break the cannula and it would not bend smoothly (see Figure 1). If you confirm the breakage of the cannula under X-ray, stop using the instrument immediately. When the broken cannula is bent repeatedly, the angle wire may be cut and may stick out of the slit (see Figure 2). This could lacerate the biliary duct.



Figure 1

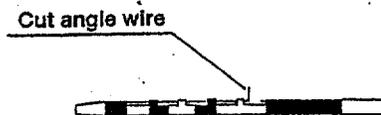


Figure 2

- Do not force the distal end of the insertion portion against body cavity tissue. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not forcibly bend the distal end, when space is restricted in a structured bile duct (see Figure 3). Doing so may detach the angle wire from the distal end of the cannula (see Figure 4). If the angle wire is detached, you will feel a series of resistance during pulling the slider (see Figure 5). When this occurs, stop using the instrument immediately and withdraw it from the endoscope without moving the slider forward. If the slider is pushed forward again after the detachment of the angle wire, it may stick out of the slit (see Figure 6). This could cause patient injury, such as perforations, hemorrhages or mucous membrane damage. If you find the angle wire detached as shown in Figure 6 after the usage of the cannula, perforations, hemorrhages or mucous membrane damage may have already occurred.

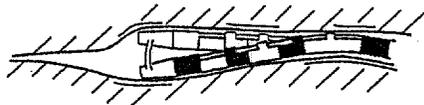


Figure 3

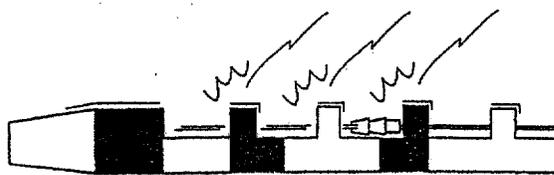


Figure 4

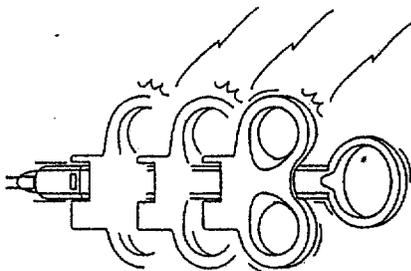


Figure 5

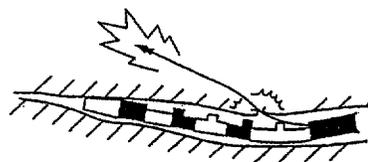


Figure 6

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Insertion into the papilla of vater and injection of the contrast medium

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WARNING

Do not forcibly insert the insertion portion into the papilla of vater. Forcible insertion could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

1. Tighten the luer fitting by turning it clockwise.
2. Connect a syringe filled with contrast medium to the injection port. Depress the syringe's plunger and confirm that the contrast medium is emitted from the distal end of the insertion portion.
3. Move the slider slowly to bend the distal end. Insert the distal end of the insertion portion into the papilla of vater.
4. Inject the contrast medium.
5. Guide the distal end of the instrument to desired area if necessary.

Withdrawing the instrument from the endoscope

WARNING

Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

CAUTION

Do not withdraw the instrument from the endoscope if the forceps elevator is up and/or while the distal end of the instrument is bent. This could damage the endoscope and/or instrument.

1. Lower the forceps elevator.
2. Reduce the angle of the instrument and withdraw the instrument from the endoscope.

Usage with guide wires

WARNING

When the guidewire has already been placed in the endoscope, be sure to hold the guidewire when inserting the instrument. Otherwise, it will move with the instrument. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

Use the instrument after reading the description below.

NOTE

- Loosen the luer fitting by turning it counterclockwise before inserting or withdrawing a guide wire into or from the instrument.
- When you inject contrast medium, confirm that the guidewire is being securely fixed by turning the luer fitting clockwise.
- If contrast medium is injected, while the coil-type guidewire is inserted, droplets of the contrast medium may adhere to the guidewire. Should this happen, wipe them off with a piece of gauze or cloth.
- If the guidewire is in place, it may be harder to bend the distal end of the instrument than if the guidewire is not in place.

10 Disposal

WARNING

- After use, dispose of the instrument in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.
- The instrument is a single-use, disposable item. Do not reuse or attempt to sterilize it. Reusing the instrument could pose an infection control risk and/or cause tissue irritation, and could not keep the function.

After using the instrument, dispose of it an appropriate manner.

DS

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Fax: (631)844-5442 Telephone: (631)844-6000

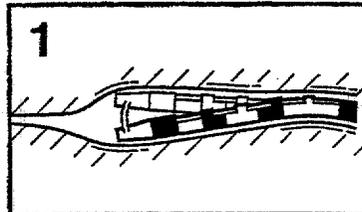
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@status.fda.hhs.gov or 301-798-8118

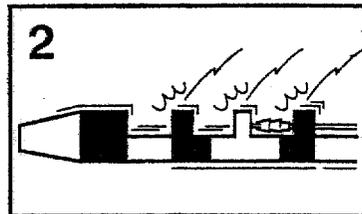
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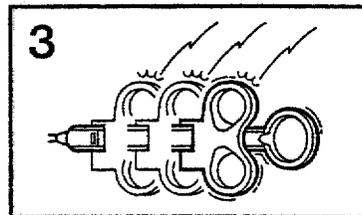
WARNING Before use, thoroughly read the instruction manual.



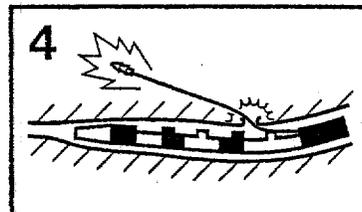
Do not forcibly bend the distal end, when space is restricted like in a strictured bile duct.



Doing so may detach the angle wire from the distal end of the cannula.



If the angle wire is detached, you will feel series of resistance.

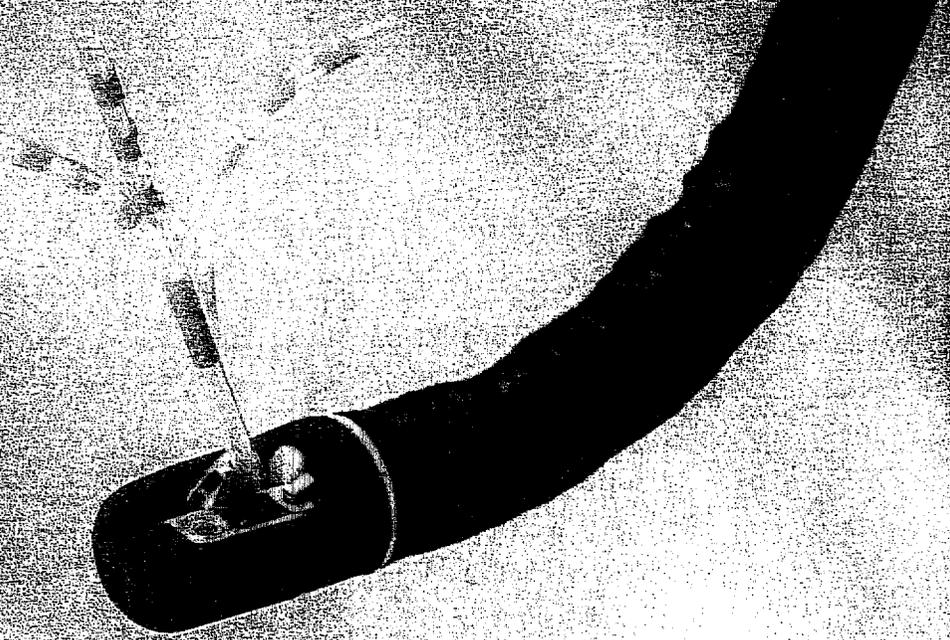


If the slider is pushed forward again after the detachment of the angle wire, it may stick out.

If the angle wire becomes detached, withdraw the instrument from the endoscope without moving the slider forward. This could cause patient injuries such as perforations, hemorrhages or mucous membrane damages.

OLYMPUS ENDOSCOPY

OLYMPUS



A Unique New Bendable Tip Which Allows Smoother,
Easier Maneuvering During ERCP Cannulation ^{3/}

ERCP Cannula

SwingTip
cannula™



OLYMPUS ENDO-THERAPY

PR-2220
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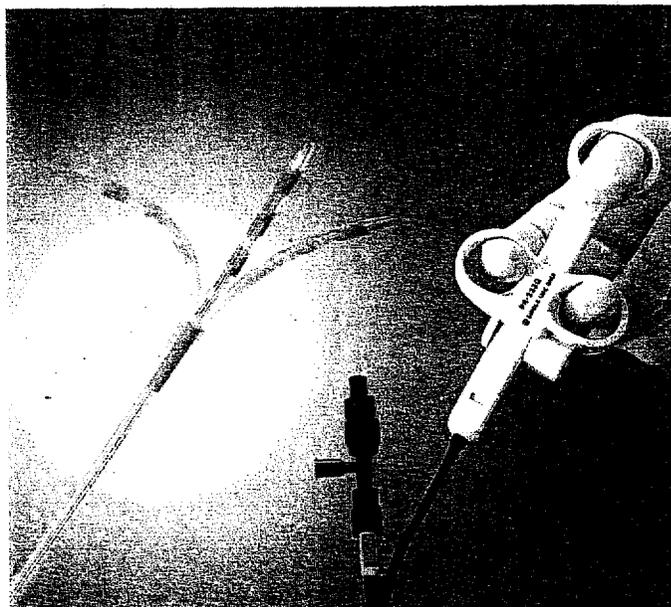
Olympus Introduces a New Cannula with Unique Tip Angulation Capability for Cases Where Cannulation is Difficult



With its innovative, breakthrough design, the PR-233Q SwingTip cannula makes the complex task of cannulation in endoscopic retrograde cholangiopancreatography easier to perform and more reliable. Featuring the tip angulation capability, the PR-233Q is easier to insert and position in the biliary ducts, allowing precise, selective maneuvering of the cannula. Even insertion of the cannula or a guide wire into the left hepatic duct is simple and straightforward.

Features

- **Angulation capability for easier insertion**
The tapered tip of the PR-233Q can be angulated by as much as 90° when the handle is pulled, and by as much as 30° when pushed, ensuring easier insertion into the papilla and the biliary ducts even in challenging cases.
- **Platinum X-ray-opaque tip**
The tip is made of platinum that offers excellent visibility under X-Ray screening, making it easy to confirm the tip position during fluoroscopy.
- **Can be combined with 0.035" guidewire**
Although the tip has a tapered design, a guidewire with a diameter of up to 0.035" (0.89 mm) can be passed through the cannula.
- **Distal markings for positional confirmation**
Blue markings placed at 3mm intervals on the distal section make it easy to confirm the depth of cannula insertion. In addition, a green marking is provided that shows when the cannula's bending section is fully extruded from the scope tip, letting you know that optimum angulation capability can now be achieved.
- **Sterile disposable design**
With an integrated short-stroke handle, the PR-233Q is sterile and disposable.



Specifications

Tip Design	Tapered	
Model	PR-233Q	
Outer Diameter	Tube	ø2.95 mm
	Distal	4.0 Fr.
Compatible Guidewire	0.035" (0.89 mm)	
Minimum Channel Diameter	ø3.2 mm	

Olympus business areas

	Medical and health-care area
	Imaging and information area
	Industrial applications area

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Attachment 2

Indications for Use Statement

510(k) Number(if known): Not assigned yet K011149

Device Name: DISPOSABLE BENDING CANNULA PR-233Q

Indications for Use:

This instrument has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

(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)

(Optional Format 1-2-96)

Attachment 3

Declaration of Conformity with Design Controls

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CONFIDENTIAL

Design Control Activities Summary

1. Main modification of the Subject Device

The subject device DISPOSABLE BENDING CANNULA PR-233Q has been modified from its predecessor to make it easier to insert the cannula into biliary and pancreatic ducts.

The subject device has been modified as compared with the predicate device, DISPOSABLE BALL TIP CANNULA PR-23Q (#K950729) or WIRE GUIDED PAPILOTOMY KNIVES KD-6G (#K950166). This modification enables the subject device to be manipulated in two directions by use of an angle wire. But the modification does not affect reliability of the diagnosis and treatment in cannulation.

2. Design Control Activities

The subject device is designed and manufactured in compliance with the in-house criteria, which is based on QSR.

We carried out risk analysis in accordance with established in-house acceptance criteria based on ISO14971-1. As a result, for safety operation, we will add the new warning about "sticking out of wire" in the instruction manual.

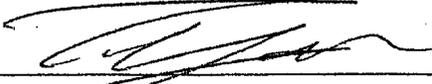
The result of our risk analysis shows that the addition of the bending function does not affect safety and effectiveness.

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A Declaration of conformity with design controls

Verification and Validation Activities

The verification and validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.



[Signature]

3. 16. 2001

[Date]

Tatsuya Yamaguchi

[TypedName]

General manager
Quality Assurance Department
Endoscope Division

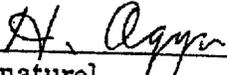
[Title]

Olympus Optical Co., Ltd

[Company]

Manufacturing Facility

The manufacturing facility, Olympus Opto-Electronics Co.,Ltd is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



[Signature]

March, 16. 2001

[Date]

Hisao Ogyu

[TypedName]

Quality Assurance Group

[Title]

Olympus Opto-Electronics Co.,Ltd

[Company]

Attachment 4

SMDA 510(k) Summary

K950729

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SMDA 510(k) SUMMARY

DISPOSABLE BENDING CANNULA PR-233Q

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer: Olympus Optical Co., Ltd.
2-3-1 Shinjuku Monolis Nishi-Shinjuku,
Shinjuku-ku Tokyo, Tokyo 163-0914
Japan
Registration No.: 8010047
Address, Phone and Fax Numbers: 2951 Ishikawa-Cho,
Of R&D Division, Hachioji-shi, Tokyo 192-8507
Endoscope Group Japan
TEL 81- 426-42-2891
FAX 81-426-46-5613

B. Name of Contact Person

Name: Laura Storms-Tyler
Address, Phone and Fax Numbers: Olympus America Inc.
Two Corporate Center Drive
Melville, New York 11747-3157
TEL: (631) 844-5688
FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name: Disposable Bending Cannula PR-233Q
Common Name: Disposable Cannula
Classification: 21 CFR 876.1500 Endoscope and accessories
21 CFR 876.5010 Biliary catheter and accessories
Predicate Device: PR-23Q DISPOSABLE BALL TIP CANNULA
K950729
KD-6G WIRE GUIDED PAPILOTOMY KNIVES
K950166

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R 011149

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D. Description of the Device(s)

The subject device is a cannula which has a bending function (angle wire), to be used in accordance with Intended Use of the Device. This bending function enables the subject device to be manipulated in 2 directions and leads to easier insertion into the biliary and pancreatic ducts.

E. Intended Use of the Device(s)

The subject device, DISPOSABLE BENDING CANNULA PR-233Q has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, this subject device Disposable bending cannula PR-233Q does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

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Attachment 5

Certification of Truthful and Accurate Statement

OLYMPUS

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required By 21 CFR 807.87(j))**

Subject Device: DISPOSABLE BENDING CANNULA PR-233Q

I certify that, in my capacity as Quality Assurance Development, Endoscope Division of Olympus Optical Co., Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Tsuyoshi Tanai
[Signature]

Tsuyoshi Tanai
[Typed Name]

Regulatory Affairs Manager
Quality Assurance Development, Endoscope Division
[Title]

Olympus Optical Co., Ltd.
[Company]

March 19, 2001
[Date]

Not assigned yet
[Premarket Notification 510(k) Number]

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