

APR 27 1995

K950700

6.0 510(k) SUMMARY FOR THE BARD® BILISYSTEM™ ERCP CANNULA

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, an adequate summary of any information respecting safety and effectiveness follows.

6.1 General Information

Name and address of submitter:

Bard Interventional Products Division
C. R. Bard, Inc.
200 Ames Pond Drive
Tewksbury, MA 01876

Contact:

John A. DeLucia
Director, Quality Assurance and Regulatory
Affairs

Date of Summary:

February 13, 1995

Name of Device:

Bard® BILISYSTEM™ ERCP Cannula

APPENDIX A

APPENDIX B

Predicate Devices:

- Wiltek E.R.C.P. Catheter (78FGE)
Wiltek Medical, Inc.
Rural Hall, NC 27045
K894867
- E.R.C.P. Cannula (78KOG)
American Endoscopy, Inc. (acquired by C.R.
Bard in 1986)
Mentor, OH 44060
K820431A
- FluoroTip™ ERCP Cannula (78KOG)
Microvasive, Inc. (Boston Scientific,
Inc.)
Watertown, MA 02172
K833417 (unable to supply a copy of
510(k))

Description and Intended Use of Device:

The 5 Fr Bard® BILISYSTEM™ ERCP Cannula is intended for cannulation of the hepatopancreatic ampulla (Papilla of Vater) for fluoroscopic visualization of the biliary/ pancreatic system. It is placed under direct vision using a side-viewing duodenoscope under fluoroscopic control. Both the straight and precurved cannula designs are provided, one per pouch, with stylet. A variety of tip designs are available. The 5 Fr outer diameter allows passage through the working channel of the endoscope, while the lumen is compatible with a 0.035 inch O.D. guidewire for

all cannula designs except the ultra taper tip configuration which is compatible with a 0.021 inch O.D. guidewire.

6.2 Summary of Similarities and Differences

Please refer to Exhibit 6.2 for a Table of Similarities and Differences between the Bard® BILISYSTEM™ ERCP Cannula and legally marketed devices.

Exhibit 6.2

Table of Similarities and Differences

Product Characteristic	Bard® BILISYSTEM™ ERCP Cannula	Wiltex ERCP Catheter K894867	E. R. C. P. Cannula American Endoscopy K820431A	FluoroTip™ Microvasive, Inc. K833417
Intended Use	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system
Straight Cannula	yes	yes	no	yes
Curved Cannula	yes	yes	yes	yes
Available tips	Standard	Standard	Standard	Standard
	Long taper	Long taper	no	no
	Short taper	Short taper	Short taper	Short taper
	Ultra Taper	no	Ultra taper	Ultra taper
	Nipple	Nipple	Nipple	no
	Ball	Ball	no	Metal (unknown type)
	Cone	Cone	no	Metal (unknown type)
Visual Markers	yes	yes	yes	yes
Radiopaque	yes - all tips	yes - all tips	no	Standard, Short taper, Ultra taper, and Metal tip
Working Length	200 cm	200 cm	200 cm	210 cm
Cannula Diameter	5 Fr	5 Fr	5.5 Fr	5 Fr - Standard and Long taper tip 5.5 Fr - Standard, Short taper, and Ball tip
Sterile	yes	yes	no	yes
Reusable	no	no	yes	no
Compatible with 0.035 inch O.D. Guidewire	yes - except Ultra taper tip is compatible with 0.021 inch O.D.	yes	Standard tip only Short and nipple tapers 0.025 inch O.D. Ultra taper 0.018 inch O.D.	yes - all except Ultra taper which is compatible with 0.025 inch O.D.
Material (tubing)	PTFE	PTFE	PTFE	PTFE
Material (luer fitting)	Polycarbonate	Polycarbonate	Nylon	unknown
Stylet	yes	yes	yes	yes

The basic product design of the Bard® BILISYSTEM™ ERCP Cannula is similar to legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. All products share the same intended use, the cannulation of the hepatopancreatic ampulla (Papilla of Vater) for fluoroscopic visualization of the biliary/pancreatic system. All are placed under direct vision using a side-viewing duodenoscope and with fluoroscopic control.

All are manufactured of PTFE and all, except the American Endoscopy predicate device, have radiopacity (metal tip or radiopaque metal markers) to allow for confirmation of device position by X-ray. All provide visual markers at the distal tip to allow assessment of the depth of insertion relative to the cannula tip.

Wiltek and Microvasive cannulas are provided in the straight and curved designs; American Endoscopy predicate device is provided in precurved design. All specified tubes are provided with a variety of tip configurations, as shown in the previous table.

All currently marketed cannulas are provided as 5 Fr. except the American Endoscopy predicate device.

All cannulas are provided in comparable lengths.

All Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas are provided with stylets.

Add To File K950700/A1

Bard Interventional Products Division
C.R. Bard, Inc.
200 Ames Pond Drive
Tewksbury, MA 01876-1286
508-851-7712

BARD

March 10, 1995

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

RECEIVED
13 MAR 95 09 01
FDA/CDRH/ODE/DMC

RE: K950700
Bard® BILISYSTEM™ ERCP Cannula
Gastroenterology - Urology Device (78KOG)

Dear Sir/Madam:

We are forwarding, as you requested, a hard copy of Manufacturer's Statement of Substantial Equivalence which was faxed to Miriam C. Provost on March 10, 1995. This has been provided in duplicate.

We trust this satisfies your request. If you should have any questions, the official Contact Person is:

John A. DeLucia
Director, QA/RA
Tel: (508) 851-7712
Fax: (508) 858-0124

Sincerely,

C. R. Bard, Inc.


John A. DeLucia
Director, QA/RA

/dlj
Enclosures

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notifications for tier 1 devices)

STATEMENT OF INDICATIONS FOR USE: The Bard^R BILISYSTEMTM ERCP Cannula
is intended for cannulation of the Papilla of Vater; fluoroscopic
visualization of the biliary/pancreatic system.

CLAIMS: None

This notification contains all of the information required by 21 CFR 807.87. A completed copy of the "DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist" is attached.

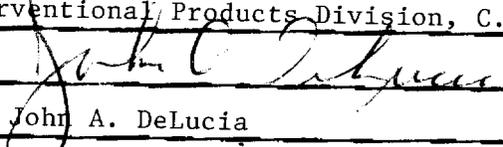
The subject device conforms to the following voluntary and mandatory standards:

Neither voluntary nor mandatory standards exist for this device.

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the subject device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)s. The kit contains no drug or biologic product.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(j)).

MANUFACTURER: Bard Interventional Products Division, C. R. Bard, Inc.

OFFICIAL CORRESPONDENT:  (signature)
John A. DeLucia (printed name)

TITLE: Director, Quality Assurance/Regulatory Affairs

DATE: March 10, 1995

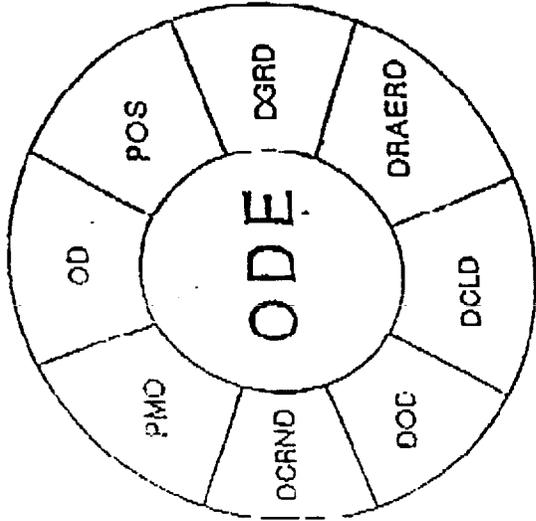
OFFICE OF DEVICE EVALUATION

DHHS/PHS/FDA/CDRH

9200 Corporate Boulevard
Rockville, MD 20850

Phone #: (301) 594- 1220

Fax #: (301) 594- 2339



TO: JOHN A. DELUCIA, DIRECTOR QA/RA

FROM: MIRIAM C. PROVOST

RE: X950700 - ERCP Cannula

Comments: Information on Triage program Enclosed. Please complete the "Manufacturers Statement of Substantial Equivalence" and fax it to me. Follow the fax with a hard copy to the document mail center.

Number of Pages: 10 17
(Including cover sheet)

Please advise if transmission is illegible.

"THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you."



APR 27 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John A. DeLucia
Director, QA/RA
C.R. Bard, Inc.
200 Amos Pond Drive
Tewksbury, Massachusetts 01876-1286

Re: K950700
Bard® BILISYSTEM™ ERCP Cannula
Dated: February 13, 1995
Received: February 15, 1995
Regulatory class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Mr. DeLucia:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the 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 may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

7a 2/17/95 RR

510(K) ROUTE SLIP

510(k) NUMBER K950700 PANEL GU DIVISION DRAER BRANCH
TRADE NAME BARD BILISYSTEM ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGR
COMMON NAME ERCP CANNULA, ENDOSCOPIC ACCESSORY
PRODUCT CODE _____

APPLICANT C.R. BARD, INC.
SHORT NAME CRBARD
CONTACT JOHN A BELUCIA
DIVISION _____
ADDRESS 200 AMES POND DRIVE
TEWKSBURY, MA 018761286
PHONE NO. (508) 851-7712 FAX NO. (____) ____-____
MANUFACTURER C.R. BARD, INC. REGISTRATION NO. 1223688

DATE ON SUBMISSION 13-FEB-95 DATE DUE TO 510(K) STAFF 01-MAY-95
DATE RECEIVED IN ODE 15-FEB-95 DATE DECISION DUE 16-MAY-95
DECISION _____ DECISION DATE _____

one predicate listed is DGRD's

2

Memorandum

Date

From

REVIEWER(S) - NAME(S) MIRIAM C. PROVOST, PH.D.

Subject

510(k) NOTIFICATION K950700

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices. - *Tier I*
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

This 510(k) contains: (check appropriate box(es))

- A 510(k) summary of safety and effectiveness, or
- A 510(k) statement that safety and effectiveness information will be made available
- The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

Predicate Product Code w/panel and class:

- ~~No Confidentiality~~
- ~~Confidentiality for 90 days~~
- ~~Continued Confidentiality exceeding 90 days~~

78 KOG 876.1500 Class II

Additional Product Code(s) w/Panel (optional):

REVIEW: GC Derrin
(BRANCH CHIEF)

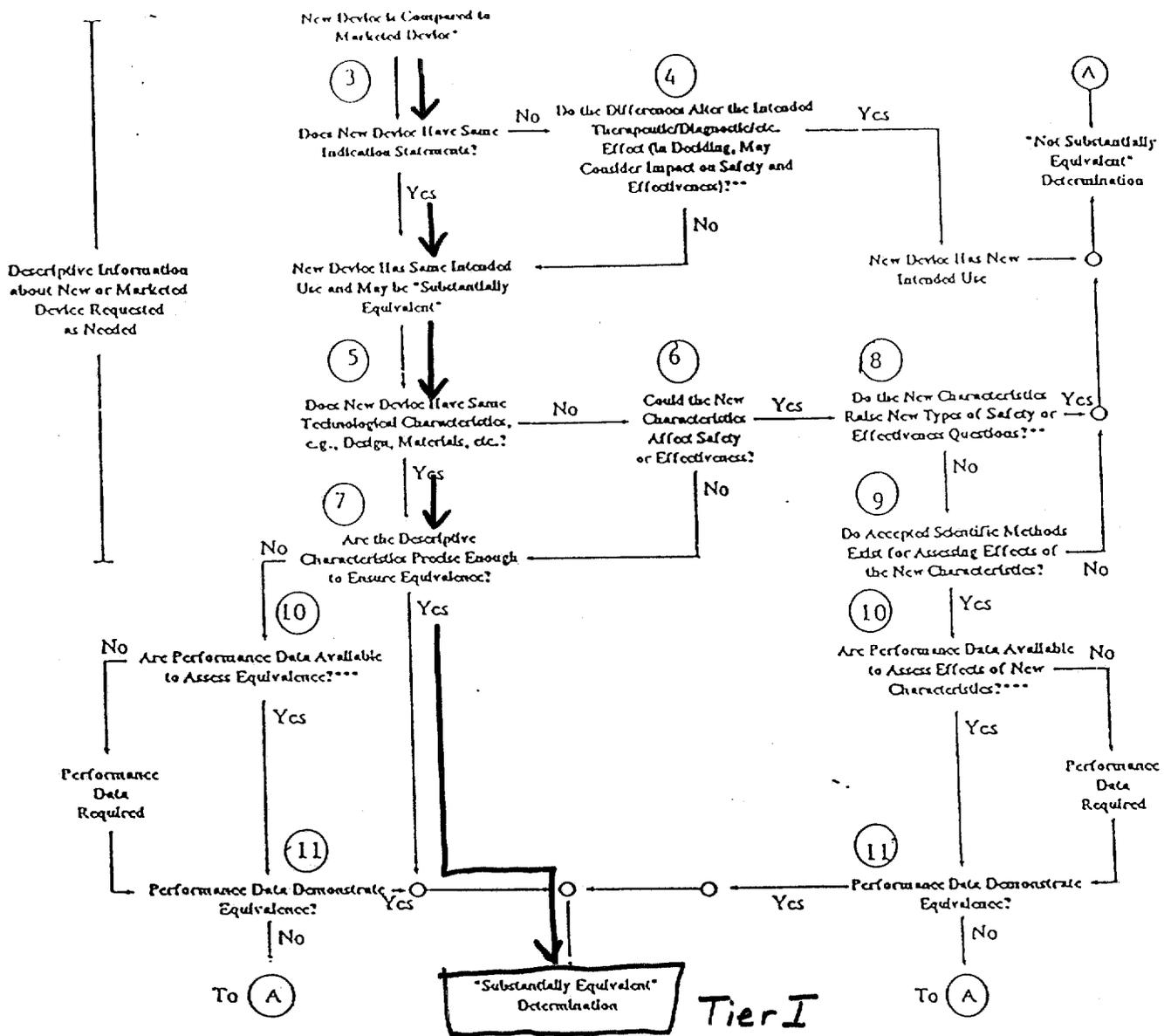
GRDB | 3/17/95
BRANCH CODE (DATE)

FINAL REVIEW: D. Pratt / L. Lin
(DIVISION DIRECTOR)

3/17/95
(DATE)

32

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

RRG/LLD 1/6/93

Rev. 9/24/93

**DRAERD Premarket Notification 510(k)
Screening Checklist**

510(k) Number &

Device Name K950700 - Bard® BILISYSTEM™ ERCP Cannula

Company C.R. Bard, Inc.

ITEM	PRESENT		NEEDED
	Yes	No	(Y/N/?)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reason for 510(k) - new device or modification	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identification of legally marketed equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Proposed Labeling, Labels, Advertisements	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of new device/modification	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intended use statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diagrams, Engineering Drawings, Photographs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Comparison of similarities/differences to named legally marketed equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Equivalent Device Labeling, Labels, Advertising	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intended use of equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. List of all patient contacting materials in new device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comparison of materials to equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Biocompatibility information/data for patient contacting materials, OR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> OR
Certification - identical material/formulation	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> NO
6. Performance data: Bench data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Animal data	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> NO
Clinical data	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> NO
7. Sterilization information	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Software validation & verification	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. 510(k) summary or statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. If Class III, Class III Certification & Summary	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> NO
11. If kit, kit certification	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> NO

52

FOR REVIEWER'S USE ONLY

RRG 9/24/93

DRAERD Premarket Notification 510(k)
SUPPLEMENTAL
Reviewer's Screening Checklist

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: K950700 TIER (Circle) I / II / III

Expedited Review Requested: Y/N Granted: Y/N OR, FDA Identified Expedited: Y/N

ITEM

- | | <u>Yes</u> | <u>No</u> |
|---|------------|-----------|
| 1. Is the product a device? | <u>X</u> | — |
| 2. Is the device exempt from 510(k) by regulation or policy? | — | <u>X</u> |
| 3. Are you aware that this device has been the subject of a previous NSE decision?
If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)? | — | <u>X</u> |
| 4. Are you aware of the submitter being the subject of an integrity investigation?
If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review? | — | <u>X</u> |
| 5. Is there a specific guidance document for this device or device issue(s)? | — | <u>X</u> |

In addition, the following item is new to the 510(k) review process. It will not be counted as a screening deficiency since it is new and "unknown" to the industry. It should be identified as a deficiency and requested as part of the technical review. The Explanation of the DRAERD Screening Checklist has been modified to include this information.

6. Address of manufacturing facility/facilities, and if applicable, sterilization site(s).

X —

Administrative Reviewer Signature: _____

Elio Mallia

Date: 2/21/95

6

DRAERD REVIEWER RECORD FOR 510(K)s, IDEs, AND PMA SUPPLEMENTS

Document Control No. K950700 Principal Reviewer PROVOST

Date Assigned 2/23/95

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>	
	<u>Yes</u>	<u>No</u>		<u>Sent</u>	<u>Returned</u>
Clinical	_____	✓	_____	_____	_____
Engineering/ Physics	_____	✓	_____	_____	_____
Chemistry/ Biomaterials	_____	✓	_____	_____	_____
Biological/ Sterility	_____	✓	_____	_____	_____
Toxicology/ Biocompatibility	_____	✓	_____	_____	_____
Statistics	_____	✓	_____	_____	_____
Other _____	_____	_____	_____	_____	_____

9

DRAERD Quality Control -- to be completed by the Associate Director and, as appropriate, by the designated Medical Officer.

A. Associate Director QC Overview -- medical QC overview of this submission is believed 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.

Medical Officer/Date
Final Signoff

Assoc. Director/Date
Final Signoff

DRAERD'S TRIAGE/TIER 1 PILOT PROGRAM
REVIEW CHECKLIST

510(k) NUMBER: K950700

CFR NO.: 876.1500 (COMPLETE ONLY IF SE)

YES OR NO

YES 1. MANUFACTURER HAS COMPLETED ALL PARTS OF
"MANUFACTURER'S STATEMENT OF SUBSTANTIAL
EQUIVALENCE" AND HAS SIGNED FORM.

YES 2. INDICATIONS FOR USE, LABELING, AND ALL CLAIMS ARE
CONSISTENT WITH PREAMENDMENT OR LEGALLY MARKETED
DEVICES.

YES 3. IF DRAERD REQUIRES CONFORMANCE TO VOLUNTARY OR
MANDATORY STANDARDS FOR THIS DEVICE, THE
MANUFACTURER HAS SUBMITTED CERTIFICATION.

IF ALL CHECKS ARE "Y", THEN 510(K) IS SUBSTANTIALLY EQUIVALENT TO
THE PREDICATE DEVICE. IF ONE ANSWER IS NO, THEN 510(K) MUST
UNDERGO TIER 2 REVIEW.

_____ OPTIONAL SPOT CHECK TIER 2 REVIEW. (WRITTEN REVIEW
ATTACHED.)

REVIEWER'S NAME Miriam C. Provost
Miriam C. Provost, Ph.D.
DATE 9/10/95

(ODE/DRAERD/PJM/LLY//DAS: 1/4/94)
(PJM 3¼ disc A:\TIER1CHK)

9

SUBSTANTIAL EQUIVALENCE (SE) DECISION MAKING DOCUMENTATION

K950700

REVIEWER: Miriam C. Provost, Ph.D

DIVISION/BRANCH: DRAERD/GRDB

TRADE NAME: Bilisystem ERCP Cannula

COMMON NAME: ERCP cannula

- | | YES | NO | |
|--|------------|-----------|------------------------------------|
| 1. Is the product a device? | ✓ | | IF NO STOP |
| 2. 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? | | | |

* per the manufacturer's Tier-1 certification statement

10

I N T E R O F F I C E M E M O R A N D U M

Date: 27-Apr-1995 08:27am EDT
From: Carl T. DeMarco
CTD
Dept: ODE-OD
Tel No: 594-2022; FAX:594-2510

TO: Marjorie G. Shulman (MYS)
CC: Heather S. Rosecrans (HSR)
CC: Lillian L. Yin (LLY)
CC: E. Carolyn Derrer (CED)

Subject: Bard 510(k) K950700

Margie, according to Section 6.1 of the referenced 510(k), it was submitted by the Bard Interventional Products Division and may be processed. The Bard AIP does not apply to this Bard Division.

Thanks for calling this to my attention.

Carl

W

MEMORANDUM

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION**

DATE: March 8, 1995

FROM: Miriam C. Provost, Ph.D., Chemical Engineer
Gastroenterology and Renal Devices Branch

SUBJECT: K950700 - C.R. Bard, Inc.
Bilisystem ERCP Cannula

TO: The Record

The following is a Tier-I review of a premarket notification submission for the above device.

1. Intended Use

The disposable Bilisystem ERCP cannula is designed to be used for cannulation and injection solutions and contrast media during endoscopic procedures, for visualization of the biliary/pancreatic system.

2. General Information Summary

Life-supporting or life-sustaining:	NO
Implant (short-term or long-term):	NO
Software-Driven:	NO
Sterility:	YES
Patient Contacting Device:	YES
Single Use:	YES
Home or Prescription Use:	NO
Drug or Biological Product:	NO

Submission Provides:

Comparative specifications:	YES
Comparative laboratory data:	YES
Summary of Animal Testing:	NO
Summary of Clinical Testing:	NO
510(k) Statement:	YES
510(k) Summary:	NO

3. Device(s) to which equivalence is claimed:

Tier - I

12

4. Device Description.

The device consists of a hollow PTFE sheath with various straight, curved or ball tip shapes.

5. Labeling

I have reviewed the labeling and the labeling is complete and consistent with what is expected for a ERCP cannula.

6. Recommendation

Substantially Equivalent - Tier 1 policy

ProCode: 78 KOG
Class: II
CFR #: 21 CFR §876.1500

Miriam C. Provost 3/10/95
Miriam C. Provost, Ph.D. Date

EC Review
3/17/95

B

Bard Interventional Products Division
C.R. Bard, Inc.
200 Ames Pond Drive
Tewksbury, MA 01876-1286
508-851-7712

BARD

March 10, 1995

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

RE: K950700
Bard® BILISYSTEM™ ERCP Cannula
Gastroenterology - Urology Device (78KOG)

Dear Sir/Madam:

We are forwarding, as you requested, a hard copy of Manufacturer's Statement of Substantial Equivalence which was faxed to Miriam C. Provost on March 10, 1995. This has been provided in duplicate.

We trust this satisfies your request. If you should have any questions, the official Contact Person is:

John A. DeLucia
Director, QA/RA
Tel: (508) 851-7712
Fax: (508) 858-0124

Sincerely,

C. R. Bard, Inc.


John A. DeLucia
Director, QA/RA

/dlj
Enclosures

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notifications for tier 1 devices)

STATEMENT OF INDICATIONS FOR USE: The Bard^R BILLISYSTEMTM ERCP Cannula
is intended for cannulation of the Papilla of Vater; fluoroscopic
visualization of the biliary/pancreatic system.

CLAIMS: None

This notification contains all of the information required by 21 CFR 807.87. A completed copy of the "DRAED Premarket Notification 510(k) Reviewer's Screening Checklist" is attached.

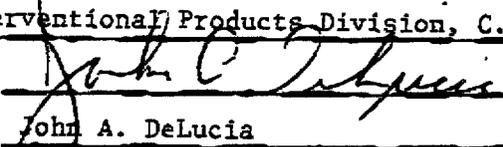
The subject device conforms to the following voluntary and mandatory standards:

Neither voluntary nor mandatory standards exist for this device.

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the subject device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)s. The kit contains no drug or biologic product.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(j)).

MANUFACTURER: Bard Interventional Products Division, C. R. Bard, Inc.

OFFICIAL CORRESPONDENT:  (signature)
John A. DeLucia (printed name)

TITLE: Director, Quality Assurance/Regulatory Affairs

DATE: March 10, 1995

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

February 16, 1995

C.R. BARD, INC.
200 AMES POND DRIVE
TEWKSBURY, MA 01876
ATTN: JOHN A. BELUCIA

510(k) Number: K950700
Received: 15-FEB-95
Product: BARD BILISYSTEM
ENDOSCOPIC
RETROGRADE
CHOLANGIOPANCREA

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.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
 - 510(k) Status Coordinator
 - Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
 - Center for Devices and Radiological Health, FDA
 - 5600 Fishers Lane
 - Rockville, Maryland 20857 USABecause of staff limitations, we cannot answer telephone status requests.
- o 510(k) status requests should include:
 - (1) submitter's name and mailing address;
 - (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

- (3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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.

B

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

19

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

_____ fax
_____ mail

A. Sponsor Information:

1. Name of 510(k) sponsor: _____

2. Sponsor's mailing address: _____

B. Requester information:

1. Request name: _____

Requester affiliation with sponsor: _____

3. Requester mailing address: _____

4. Request fax number (if applicable): _____

5. Requester telephone number: _____

C. 510(k) information:

1. Product name: _____

2. 510(k) number: _____

3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

.....
I certify that the above information is accurate and truthful to the best of my knowledge.

Bard Interventional Products Division
C.R. Bard, Inc.
200 Ames Pond Drive
Tewksbury, MA 01876-1286
508-851-7712

1 K950700
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BARD

VIA FEDERAL EXPRESS

February 13, 1995

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

RECEIVED
15 FEB 95 08 45
FDA/CDRH/OOE/DHC

Re: Premarket Notification for
Bard® BILISYSTEM™ ERCP Cannula
Gastroenterology-Urology Device (78KOG)

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, Bard Interventional Products Division, C.R. Bard, Inc. is submitting two copies of the 510(k) notification for the Bard® BILISYSTEM™ Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannula and two copies of this cover letter.

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.

Section 1.0 of this document contains a copy of the "Premarket Notification [510(k)] Checklist for Acceptance Decision," with reference to the Section of this document that contains the required information. The 510(k) Summary of Safety and Effectiveness Information can be found in Section 6.0.

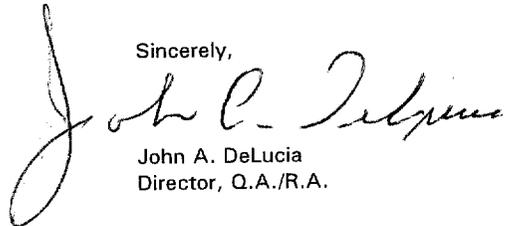
It is the understanding of C.R. Bard, Inc. that written notification will be received from FDA if this device is subject to Section 522 of the Federal Food, Drug and Cosmetic Act, i.e., Postmarket Surveillance.

C.R. Bard, Inc. 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, C.R. Bard, Inc. requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b). C.R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions about this notification, the Contact Person is:

John A. DeLucia
Tel: (508) 851-7712
Fax: (508) 858-0124

Sincerely,



John A. DeLucia
Director, Q.A./R.A.

/dlj
Enclosures



510(k) Premarket Notification
for
Bard® BILISYSTEM™ ERCP Cannula

TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
1.0 PREMARKET NOTIFICATION CHECKLIST FOR ACCEPTANCE DECISION AND REQUIRED INFORMATION.....	3
2.0 INTRODUCTION.....	7
2.1 Background.....	10
3.0 DEVICE DESCRIPTION.....	11
3.1 Device Design.....	11
Exhibits 3.1A and 3.1B - Device Engineering Drawings	
3.2 Major Components and Materials.....	18
3.3 Principles of Operation.....	19
3.4 Packaging and Sterilization.....	20
3.5 Intended Use.....	21
3.6 Device Photographs.....	21
4.0 STATEMENT OF SUBSTANTIAL EQUIVALENCE.....	23
4.1 Summary of Similarities and Differences.....	23
Exhibit 4.1 - Table of Substantial Equivalence	
4.2 Substantial Equivalence Decision Tree.....	26
Exhibit 4.2 - 510(k) "Substantial Equivalence" Decision Making Process	
5.0 PRODUCT LABELING.....	30
5.1 Draft Unit Label.....	30
5.2 Draft Information for Use.....	37
5.3 Proposed Product Brochure.....	39
6.0 510(k) SUMMARY FOR THE BARD® BILISYSTEM™ ERCP CANNULA.....	41
6.1 General Information.....	41
6.2 Summary of Similarities and Differences.....	43
6.3 Substantial Equivalence Decision Tree.....	46

APPENDICES

Appendix A -	Bench Testing.....	50
Appendix B -	Biocompatibility Tests.....	56
Appendix C -	Predicate Device Information.....	70
Appendix C1 -	Wiltek Medical, Inc. Premarket Notification K894867.....	71
Appendix C2 -	American Endoscopy, Inc. Premarket Notification K820431A.....	77
Appendix C3 -	Wiltek Medical, Inc. ERCP Device Labeling.....	94
Appendix C4 -	American Endoscopy, Inc. ERCP Device Labeling.....	96
Appendix C5 -	Microvasive, Inc. ERCP Device Labeling.....	98

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2

22

SECTION 1.0

PREMARKET NOTIFICATION [510(k)] CHECKLIST
FOR ACCEPTANCE AND REQUIRED INFORMATION

- I. CRITICAL ELEMENTS
- II. REQUIRED INFORMATION
- III. ADDITIONAL INFORMATION



1.0 PREMARKET NOTIFICATION [510(k)] CHECKLIST FOR
ACCEPTANCE DECISION AND REQUIRED INFORMATION

I. **CRITICAL ELEMENTS**

The Bard® BILISYSTEM™ Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannula is a device, as defined in Section 201 of the Federal Food, Drug and Cosmetic Act, as Amended (the Act), which is not exempt from 510(k) requirements, by regulation or by policy, and is subject to review by CDRH. This device has never been the subject of a previous "Not Substantially Equivalent" Decision.

II. **REQUIRED INFORMATION (under Sections 510(k), 513(f), and 512(i) of the Act, and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations)**

a. Device trade or proprietary name:	Bard® BILISYSTEM™ Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannula
b. Device common or usual name, or classification name:	ERCP Cannula, Endoscopic Accessory (78KOG)
c. Establishment registration number:	#1223688, #1526170
Owner/operator number	C. R. Bard, Inc., #2212754
d. Class into which the device is classified under 21 CFR 876:	This device has not been classified under 21 CFR 876. It is used as an accessory to a duodenoscope, a Class II device.
e. Classification Panel:	Gastroenterology-Urology Devices
f. Action taken to comply with Section 514 of the Act:	No standard presently exists for this device.

dy

g. Proposed labels, labeling, Instructions for Use, advertisements (if available) that describe the device, its intended use, and directions for use:	See Section 5.0
h. 510(k) Safety and Effectiveness Information:	A summary of safety and effectiveness information has been provided in Section 6.0
i. For Class III devices only, a Class III Certification and a Class III Summary:	Not Applicable
j. Photographs of the device:	See Section 3.6
k. Engineering drawings for the device with dimensions and tolerances:	See Section 3.1
l. The marketed device(s) to which equivalence is claimed including labeling and description of the device:	See Section 4.0 and Appendix C
m. Statement of similarities and/or differences with the marketed devices:	See Section 4.0
n. Data to show consequences and effects of a modified device:	Not Applicable

III. ADDITIONAL INFORMATION that is necessary under 21 CFR 807.87(b):

a. Submitter's name and address:	John A. DeLucia, Director, Q.A./R.A. Bard Interventional Products Division 200 Ames Pond Drive Tewksbury, MA 01876
b. Contact person, telephone number, and fax number:	John A. DeLucia, Director, Q.A./R.A. Bard Interventional Products Division 200 Ames Pond Drive Tewksbury, MA 01876 Tel: 1-508-851-7712 FAX: 1-508-858-0124
c. Representative/Consultant, if applicable:	Not Applicable
d. Table of Contents with pagination:	See Page 1 of this document
e. Manufacturing Facility/Facilities (Name and address):	Bard Interventional Products 200 Ames Pond Drive Tewksbury, MA 01876 Registration #1223688 and/or Bard Interventional Products 9350 Progress Parkway Mentor, OH 44060 Registration #1526170
f. Sterilization Site(s) Name and Address:	See Section 3.4

BB

III. ADDITIONAL INFORMATION that may be necessary under 21 CFR 807.87(h) :

a.	Comparison table of the new device to the marketed device:	See Section 4.0
b.	Action taken to comply with voluntary standards:	No standards presently exist for this device.
c.	Performance data: Bench testing Biocompatibility	Appendix A Appendix B
d.	Sterilization information:	See Section 3.4
e.	Software information:	Not applicable; No software is utilized with this device.
f.	Hardware information:	Not applicable; No hardware is utilized with this device.
g.	Is the device subject to issues that have been addressed in specific guidance documents?	Bard Interventional Products is not aware of any device-related issues which have been addressed in specific guidance documents.

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2

SECTION 2.0

INTRODUCTION

2.1 Background

2.0 INTRODUCTION

In compliance with Section 510(k) of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, C.R. Bard, Inc. hereby notifies the Food and Drug Administration of its intent to introduce the Bard® BILISYSTEM™ Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannula into interstate commerce for commercial distribution. As outlined below, Bard Interventional Products Division, C.R. Bard, Inc. believes this product is substantially equivalent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas, specifically the following products:

- Wiltek E.R.C.P. Catheter (78FGE)
Wiltek Medical, Inc.
Rural Hall, NC 27045
K894867
- E.R.C.P. Cannula (78KOG)
American Endoscopy, Inc. (acquired by C.R. Bard in 1986)
Mentor, OH 44060
K820431A
- FluoroTip™ ERCP Cannula (78KOG)
Microvasive, Inc. (Boston Scientific, Inc.)
Watertown, MA 02172
K833417 (unable to supply a copy of 510(k))

This premarket notification has been submitted because Bard Interventional Products Division, C.R. Bard, Inc. wishes to modify and extend its current line of Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas which were in 1986 acquired from American Endoscopy, Inc. These Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannulas are currently marketed by C.R. Bard Interventional Products.

The proposed changes and modifications to this line extension include:

1. To allow for the use of long taper tip configuration with the pre-curve cannula design. The existing line includes standard, nipple, taper (short) and ultra taper tip configurations.
2. To allow for the use of two (2) metal tip configurations i.e., ball and cone tip with the pre-curve cannula design. Existing line has no metal tip configurations.
3. To allow for the use of straight cannulas with the same tip configurations as the pre-curve, both existing and proposed. Existing line has pre-curved cannula design only.
4. To slightly reduce shaft French size from 5.5 to 5.0.
5. To allow for sterile, single use disposable product. Existing product is labeled non-sterile and single use.
6. To allow compatibility with a 0.035 inch O.D. guidewire on all cannula designs, except the ultra taper tip configuration which is compatible with an 0.021 inch O.D. guidewire. Existing line requires a variety of guidewire sizes depending on tip design.
7. To allow for the use of a polycarbonate luer. Existing line contains a nylon luer.
8. To allow for the tips of the cannulas, both straight and pre-curve designs, to be radiopaque. Existing line is non-radiopaque.

All of these changes and modifications are based upon customer and user preference. They are not in response to complaints or problems.

89

2.1 Background

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a diagnostic procedure which is performed using a side-viewing fiberoptic duodenoscope and under fluoroscopic control in patients with suspected biliary and pancreatic pathology. The Endoscopic Retrograde Cholangiopancreatography (ERCP) cannula, introduced into the hepaticopancreatic ampulla (Papilla of Vater), is used to deliver contrast media for fluoroscopic visualization of the biliary/pancreatic system.

Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas are currently available in two basic designs, straight and precurved. The precurved cannula more closely follows common bile duct (CBD) anatomy, thereby facilitating cannulation. The cannula is a single lumen polytetrafluoroethylene tube (PTFE) with a radiopaque tip and an outside diameter of 5 Fr., which is compatible with the 2.8 mm working channel of the duodenoscope. The internal diameter is compatible with the passage over a standard 0.035 inch diameter guidewire for straight and pre-curve designs and 0.021 inch diameter guidewire for the ultra taper tip design. A variety of distal tip configurations are provided. The distal tip is marked, allowing visual assessment of insertion depth relative to the cannula tip. A radiopaque marker (or the metal cannula tips) at the distal end of the cannula is used for orientation during fluoroscopy. The proximal adapter is provided with two luer fittings: one for the insertion of the metal stylet which provides stiffness during insertion, and the second for the attachment of the syringe containing the contrast agent.

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SECTION 3.0

DEVICE DESCRIPTION

- 3.1 Device Design
- 3.2 Major Components and Materials
- 3.3 Principles of Operation
- 3.4 Packaging and Sterilization
- 3.5 Intended Use
- 3.6 Device Photographs

31

3.0 DEVICE DESCRIPTION

3.1 Device Design

All dimensions of the Bard® BILISYSTEM™ ERCP Cannula described below are **nominal** (in inches) except where noted otherwise. Engineering drawings are provided in Exhibits 3.1A and 3.1B, with device photographs presented in Section 3.6. **The code numbers appearing in parentheses in descriptions below refer to the Item Numbers on the device drawings in Exhibits 3.1A and 3.1B.**

The 5 Fr Bard® BILISYSTEM™ ERCP Cannula is available in straight and precurved designs, provided packaged with the stylet wire. Detailed descriptions of the Bard® BILISYSTEM™ ERCP Cannula and stylet are provided below, with engineering drawings as follows:

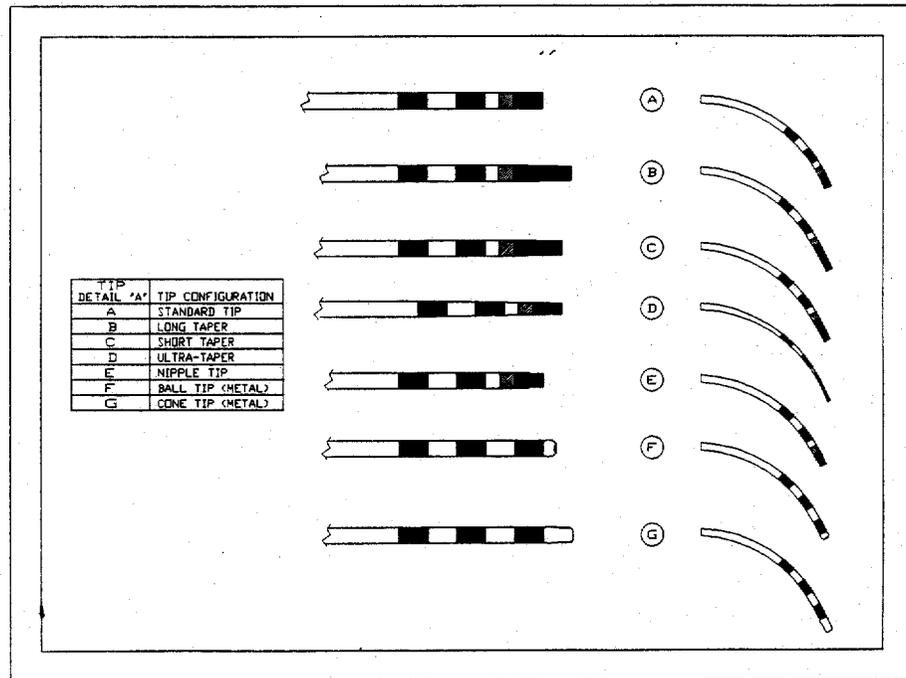
- Bard® BILISYSTEM™ ERCP Cannula, Straight (Exhibit 3.1A)
- Bard® BILISYSTEM™ ERCP Cannula, Precurved (Exhibit 3.1B)

The Bard® BILISYSTEM™ ERCP Cannula is available only in a 5 Fr (0.066 inch/1.7 mm O.D.) shaft, allowing insertion into the 2.8 mm diameter biopsy channel of a duodenoscope. Both the straight and the precurved cannulas have a usable length of 200 cm and consist of the following parts: the single lumen tubing (1), shrink tubing (2), and the proximal luer fitting (3). Cannulas with the distal ball or cone tip have the additional metal tip (4) inserted into the distal lumen. A radiopaque metal marker (5) is added to cannulas without metal tips. Lastly, the stylet wire, consisting of a stylet hub (6) and stylet wire (7)

provides rigidity to the tubing during the cannulation procedure.

Tubing, single lumen (1): The shaft of the Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannula is single lumen extruded PTFE. The tubing O.D. is 0.066 inches to allow passage through the working channel of the duodenoscope. The tubing has an I.D. of 0.037 inch, compatible with passage over a commercially available standard 0.035 inch (O.D.) guidewire; however, the ultra taper tip configuration is the only design requiring an 0.021 inch (O.D.) guidewire. The proximal end of the tube is bonded to the proximal luer fitting.

The distal tip of the cannula is provided in the following designs and tip configurations.



The distal tip configurations of standard, long taper, short taper, ultra-taper and nipple tip

[Handwritten signature]

have varying tapers to offer the endoscopist a greater selection in cannulas.

The distal end of the PTFE tubing is marked at alternating intervals with visual markers to allow the endoscopist to visually determine the depth of insertion relative to the cannula tip.

Shrink Tubing (2): The shrink tubing is opaque polyolefin which acts as a strain relief to the shaft at the junction of the luer when a syringe is attached.

Proximal Luer Fitting (3): The proximal luer fitting is injection molded polycarbonate with two luer ports. The main port is used for the stylet while the side port connects to the syringe holding the contrast agent. The proximal end of the tubing (1) is bonded to the luer fitting. The side luer is provided with a cap which is used to occlude the luer when not in use. The proximal luer fittings for the straight and precurved Bard® BILISYSTEM™ ERCP Cannulas are identical.

Metal tip (4): Metal tips, made of 304 stainless steel, are used for ball and cone tip cannulas. Both are mechanically threaded on to the PTFE cannula tubing.

Ball tip: The ball tip has an O.D. of 0.072 inches and an I.D. of 0.038 inches.

Cone tip: The cone tip has an O.D. of 0.072 inches and an I.D. of 0.038 inches.

Radiopaque Marker (5):

Cannulas without metal tips are provided with a radiopaque 304 stainless steel or tantalum marker,

located 3 to 6 mm from the end of the cannula, for fluoroscopic and radiographic orientation. The exact location of these markings is provided on the engineering drawings (Exhibits 3.1 A and 3.1B).

ell

Stylet

The Bard® BILISYSTEM™ ERCP Cannula is provided with a stylet, providing rigidity to the PTFE tubing during the cannulation procedure. The stylet supplied with the straight is identical to that supplied with the precurved design. It consists of the **stylet hub (6)** and the **stylet wire (7)**. The usable length of the stylet is 90 cm. An engineering drawing of the stylet is provided as Exhibit 3.1A and 3.1B.

Stylet Hub (6): The hub is an injection molded polycarbonate plug bonded to the proximal end of the stylet wire. It is provided to allow for easy removal of the stylet from the cannula.

Stylet Wire (7): The stylet wire is composed of T302 or 304 stainless steel wire with an O.D. of 0.020 inches.

EXHIBIT 3.1A
Engineering Drawing
Bard® BILISYSTEM™ ERCP Cannula, Straight

JB

EXHIBIT 3.1B
Engineering Drawing
Bard® BILISYSTEM™ ERCP Cannula, Precurved

CT

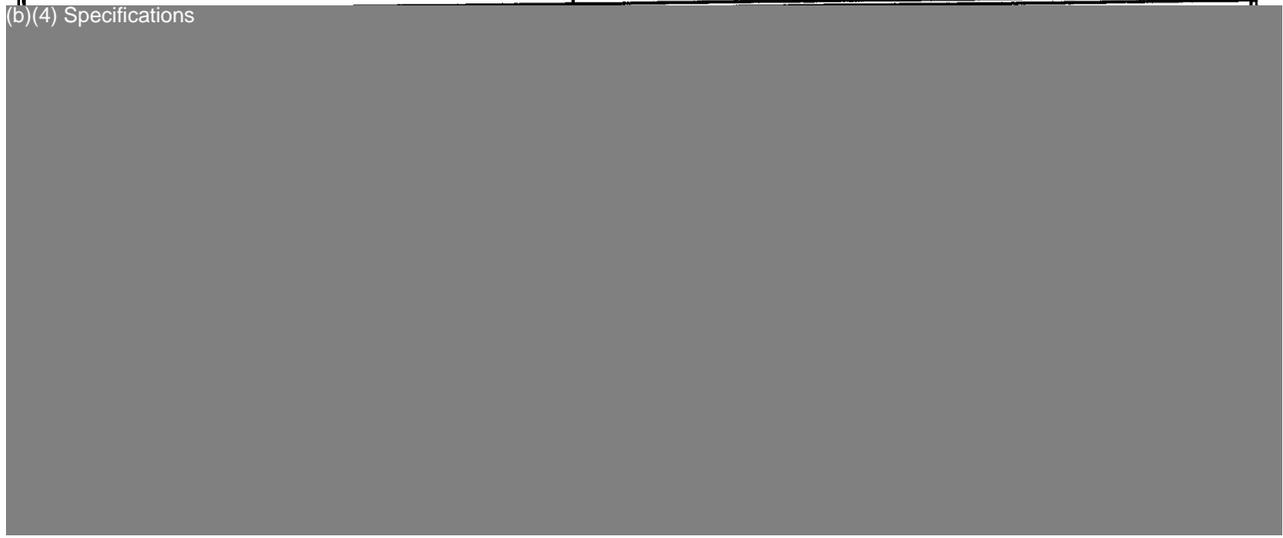
3.2 Major Components and Materials

The table below summarizes the components and materials of the Bard® BILISYSTEM™ ERCP Cannula and Stylet.

All materials described below are also specified in the device drawings in Exhibits 3.1A and 3.1B. Biocompatibility testing is provided in Appendix B.

Component	Chemical Description	Commercial Description
-----------	----------------------	------------------------

(b)(4) Specifications



3.3 Principles of Operation

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a diagnostic procedure performed under fluoroscopic control in patients with suspected biliary and pancreatic pathology. The cannula, used to deliver a contrast agent, is introduced into the hepatopancreatic ampulla (Papilla of Vater) using a side viewing duodenoscope.

The Bard® BILISYSTEM™ ERCP Cannula is intended for cannulation of the hepatopancreatic ampulla (Papilla of Vater) to deliver contrast material for fluoroscopic visualization of the biliary/pancreatic system.

Bard® BILISYSTEM™ ERCP Cannula is available in 5 Fr with both straight and precurved designs. Both designs are provided with the following distal tip configurations:

- standard
- long taper
- short taper
- ultra taper
- nipple taper
- ball tip (metal)
- cone tip (metal)

Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannula, lumen size is compatible with the standard 0.035 inch (O.D.) guidewire. The ultra taper tip configuration cannula is compatible with a 0.021 inch (O.D.) guidewire.

The cannula is placed using a side viewing duodenoscope under fluoroscopic control. A brief description of the placement technique is provided below. Detailed Information for Use of the Bard®

BILISYSTEM™ ERCP Cannula are provided in product labeling in Section 5.0.

The Endoscopic Retrograde Cholangiopancreatography (ERCP) Cannula is placed under direct vision and fluoroscopic control using a side-viewing duodenoscope. The duodenoscope is passed through the pylorus and the duodenal bulb. The hepatopancreatic ampulla (Papilla of Vater) is identified. The cannula is advanced through the biopsy channel of the duodenoscope and passed through the Sphincter of Oddi at the papillary orifice. A guidewire may be inserted through the cannula to provide support during insertion and facilitate cannulation of the ampulla. Cannula position is assessed visually and with fluoroscopy. Once through the orifice, the biliary/pancreatic system is visualized by injection of radiopaque contrast through the side luer of the adaptor.

3.4 Packaging and Sterilization

3.4.1 Packaging

The packaging materials and methods used for Bard® BILISYSTEM™ ERCP Cannula are typical throughout the medical device industry. The Bard® BILISYSTEM™ ERCP Cannula is packaged as a single unit in an 8 inch x 12 inch Tyvek-Mylar pouch. The top of the pouch, outside the sealing chevron, is provided with a hole to allow hanging storage.

Packaging Procedure:

The Bard® BILISYSTEM™ ERCP Cannula, with the stylet and cap in place, is coiled upon itself.

The folded Information for Use is added. The pouch is sealed and labeled.

3.4.2 Sterilization

The Bard® BILISYSTEM™ ERCP Cannula will be sterilized in a validated Ethylene Oxide (EtO) cycle to a SAL of 1×10^{-6} , using the Association for the Advancement of Medical Instrumentation (AAMI) Guidelines for Ethylene Oxide Sterilization Validation (AAMI March 31, 1988, "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices"). Sterilization will be contracted to Ethox Corp., Buffalo, NY, and/or their sister company, Medical Manufacturing Corp., Erie, PA. Bard® BILISYSTEM™ ERCP Cannula shall meet the maximum allowable EtO residual levels (ethylene oxide, ethylene chlorohydrin, and ethylene glycol) for devices contacting mucosa as proposed by FDA in the Federal Register of June 23, 1978 (250 ppm, 250 ppm, and 5000 ppm respectively).

3.5 Intended Use

The Bard® BILISYSTEM™ ERCP Cannula is intended for cannulation of the hepatopancreatic ampulla (Papilla of Vater) to deliver contrast material for fluoroscopic visualization of the biliary/pancreatic system.

3.6 Device Photographs

The photographs of the proposed device/s are presented as follows:

Photograph 3.6.1 The finished device, Bard®
BILISYSTEM™ ERCP Cannula in the
pouch

Photograph 3.6.2 The finished device, Bard®
BILISYSTEM™ ERCP Cannula removed
from the pouch

Photograph 3.6.1
Finished Device in the Pouch



ERCP CANNULA
Pre-Curved 5FR
Short Taper Tip
LISYSTEM
USE COMPLETELY

Bard ERCP Cannula
Pre-Curved
Short Taper Tip
Recorder No. 050330

ITEM DESCRIPTION	UNITS
PRE-CURVED	1.00
SHORT TAPER TIP	1.00

CONTACT: 1 Unit, Lot # 1000000
Read Carefully: Information for Use Prior to Use
Caution: Sterile. Do not use unless the device is
shown to be free of defects.
STERILE unless otherwise noted or managed
Single Patient Use
Bard is a registered trademark of
Bard Inc. or its subsidiaries.

BARD

Bard ER

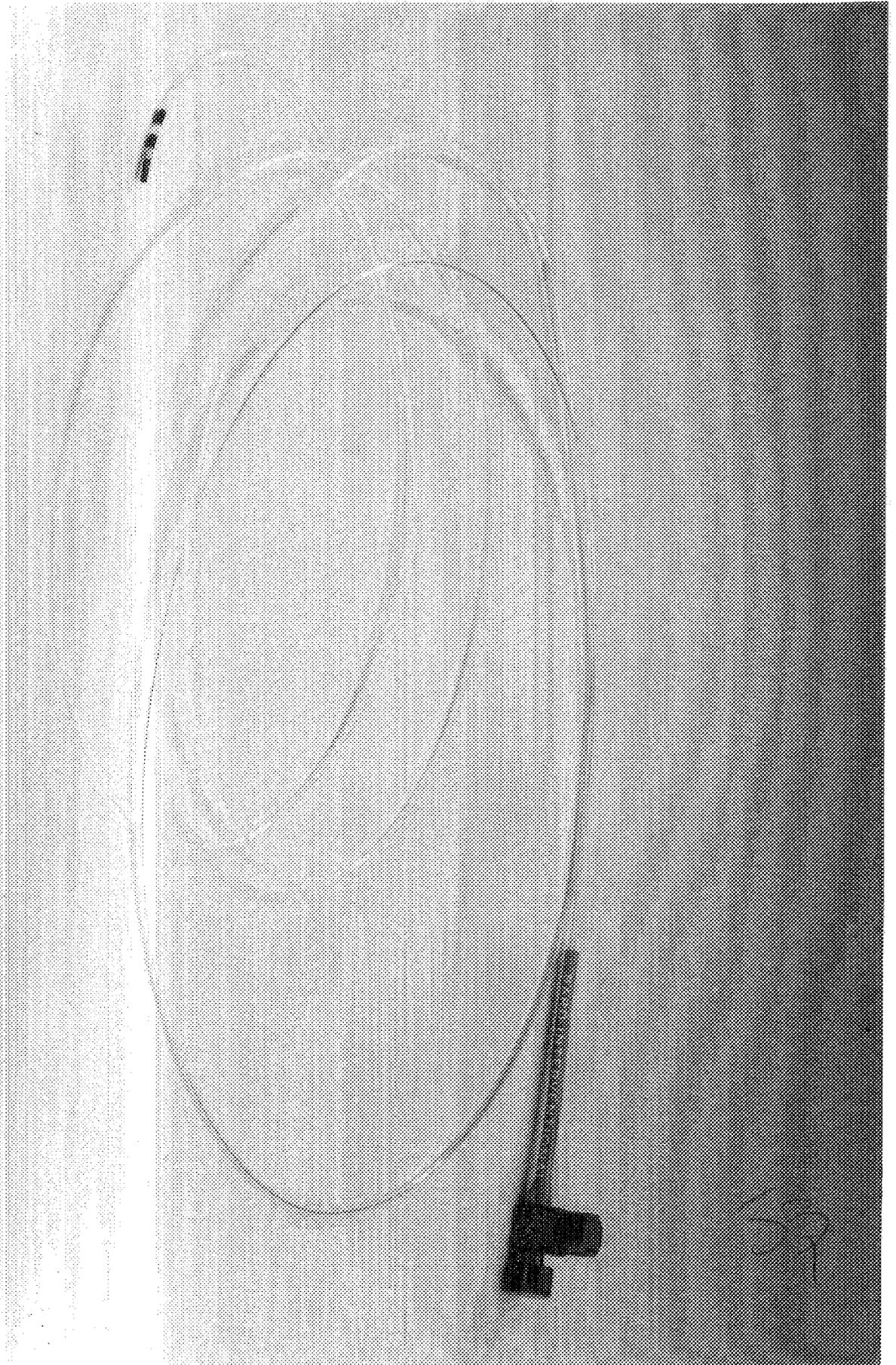
Information For Use

Caution: Do not use unless the device is shown to be free of defects.

62

Photograph 3.6.2

----- Finished Device Removed from Pouch-----



4

54

SECTION 4.0

STATEMENT OF SUBSTANTIAL EQUIVALENCE

- 4.1 Summary of Similarities and Differences
- 4.2 Statement of Substantial Equivalence

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4.0 STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to the following legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas:

- Wiltek E.R.C.P. Catheter (78FGE)
Wiltek Medical, Inc.
Rural Hall, NC 27045
K894867
- E.R.C.P. Cannula (78KOG)
American Endoscopy, Inc. (acquired by C.R. Bard in 1986)
Mentor, OH 44060
K820431A
- FluoroTip™ ERCP Cannula (78KOG)
Microvasive, Inc. (Boston Scientific, Inc.)
Watertown, MA 02172
K833417

4.1 Summary of Similarities and Differences

Please refer to Exhibit 4.1 for the Table of Substantial Equivalence which summarizes the similarities and differences between the Bard® BILISYSTEM™ ERCP Cannula and legally marketed devices. Exhibits 3.1A and 3.1B contain engineering drawings for the proposed device/s.

Exhibit 4.1
Table of Substantial Equivalence

SU
DGRD
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Product Characteristic	Bard® BILISYSTEM™ ERCP Cannula	Wiltex ERCP Catheter K894867	E.R.C.P. Cannula American Endoscopy K820431A	FluoroTip™ Microvasive, Inc. K833417
Intended Use	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system
Straight Cannula	yes	yes	no	yes
Curved Cannula	yes	yes	yes	yes
Available tips	Standard	Standard	Standard	Standard
	Long taper	Long taper	no	no
	Short taper	Short taper	Short taper	Short taper
	Ultra taper	no	Ultra taper	Ultra taper
	Nipple	Nipple	Nipple	no
	Ball	Ball	no	Metal (unknown type)
	Cone	Cone	no	Metal (unknown type)
Visual Markers	yes	yes	yes	yes
Radiopaque	yes - all tips	yes - all tips	no	Standard, Short taper, Ultra taper, and Metal tip
Working Length	200 cm	200 cm	200 cm	210 cm
Cannula Diameter	5 Fr	5 Fr	5.5 Fr	5 Fr
Sterile	yes	yes	no	yes
Reusable	no	no	yes	no
Compatible with 0.035 inch O.D. Guidewire	yes - except Ultra taper tip is compatible with 0.021 inch O.D.	yes	Standard tip only Short and nipple tapers 0.025 inch O.D. Ultra taper 0.018 inch O.D.	yes - all except Ultra taper which is compatible with 0.025 inch O.D.
Material (tubing)	PTFE	PTFE	PTFE	PTFE
Material (luer fitting)	Polycarbonate	Polycarbonate	Nylon	unknown
Styilet	yes	yes	yes	yes

The basic product design of the Bard® BILISYSTEM™ ERCP Cannula is similar to legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. All products share the same intended use, the cannulation of the hepatopancreatic ampulla (Papilla of Vater) for fluoroscopic visualization of the biliary/pancreatic system. All are placed under direct vision using a side-viewing duodenoscope and with fluoroscopic control.

All are manufactured of PTFE and all, except the American Endoscopy predicate device, have radiopacity (metal tip or metal marker) to allow for confirmation of device position by X-ray. All provide visual markers at the distal tip to allow assessment of the depth of insertion relative to the cannula tip.

Wiltek and Microvasive cannula are provided in the straight and curved designs. The American Endoscopy predicate device is provided only in the precurved design. All specified tubes are provided with a variety of tip configurations.

All currently marketed cannulas are provided as 5 Fr, except the American Endoscopy predicate device, and in comparable lengths.

All Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas are provided with stylets.

Although there may be minor differences in device manufacture and packaging, the proposed Bard® BILISYSTEM™ ERCP Cannula is substantially equiva-



lent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. Any difference between products raises no issue of safety and effectiveness.

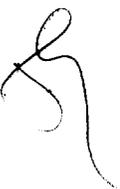
4.2 Statement of Substantial Equivalence

The Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas specifically those manufactured by Wiltek Medical, Inc., American Endoscopy, and Microvasive, Inc. Competitive product information for these manufacturers and products is provided in Appendix C of this premarket notification.

A summary of the similarities and differences between the Bard® BILISYSTEM™ ERCP Cannula and those manufactured by Wiltek Medical, Inc., American Endoscopy, and Microvasive, Inc. is provided in Exhibit 4.1 above, "Table of Substantial Equivalence."

The 510(k) "Substantial Equivalence" Decision-making Process (Detailed) in ODE Guidance #K86-3, Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence. Please refer to Exhibit 4.2 for a diagram of the 510(k) Decision Tree. The answers to the questions lead to a determination of substantial equivalence.

1. Does the new device have the same indication statement?



Yes. The Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas with respect to intended use. It is intended for cannulation of the hepatopancreatic ampulla (Papilla of Vater) for fluoroscopic visualization of the biliary/pancreatic system.

2. Does the new device have the same technological characteristics, e.g. design, materials, etc.?

Yes. The Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas with respect to technological characteristics (design, materials, etc.). All consist of a proximal luer adaptor, tubing, and a variety of tip shapes. Straight and precurved cannula designs are available.

All cannulas consist of PTFE tubing with various materials used for connectors. All utilize tip marking to allow visual assessment of depth of insertion relative to cannula tip. All provide radiopaque markers for orientation on fluoroscopy except the American Endoscopy predicate device. Materials for the Bard® BILISYSTEM™ ERCP Cannula have been shown to be nontoxic and biocompatible, as provided in Appendix B of this premarket notification.

3. Are the descriptive characteristics precise enough to ensure equivalence?



Yes. A comparison of the key properties of intended use, design and materials are presented in the "Table of Substantial Equivalence", Exhibit 4.1. This table compares the Bard® BILISYSTEM™ ERCP Cannula to legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. The table has been developed to support the determination that the proposed Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to those legally marketed products.

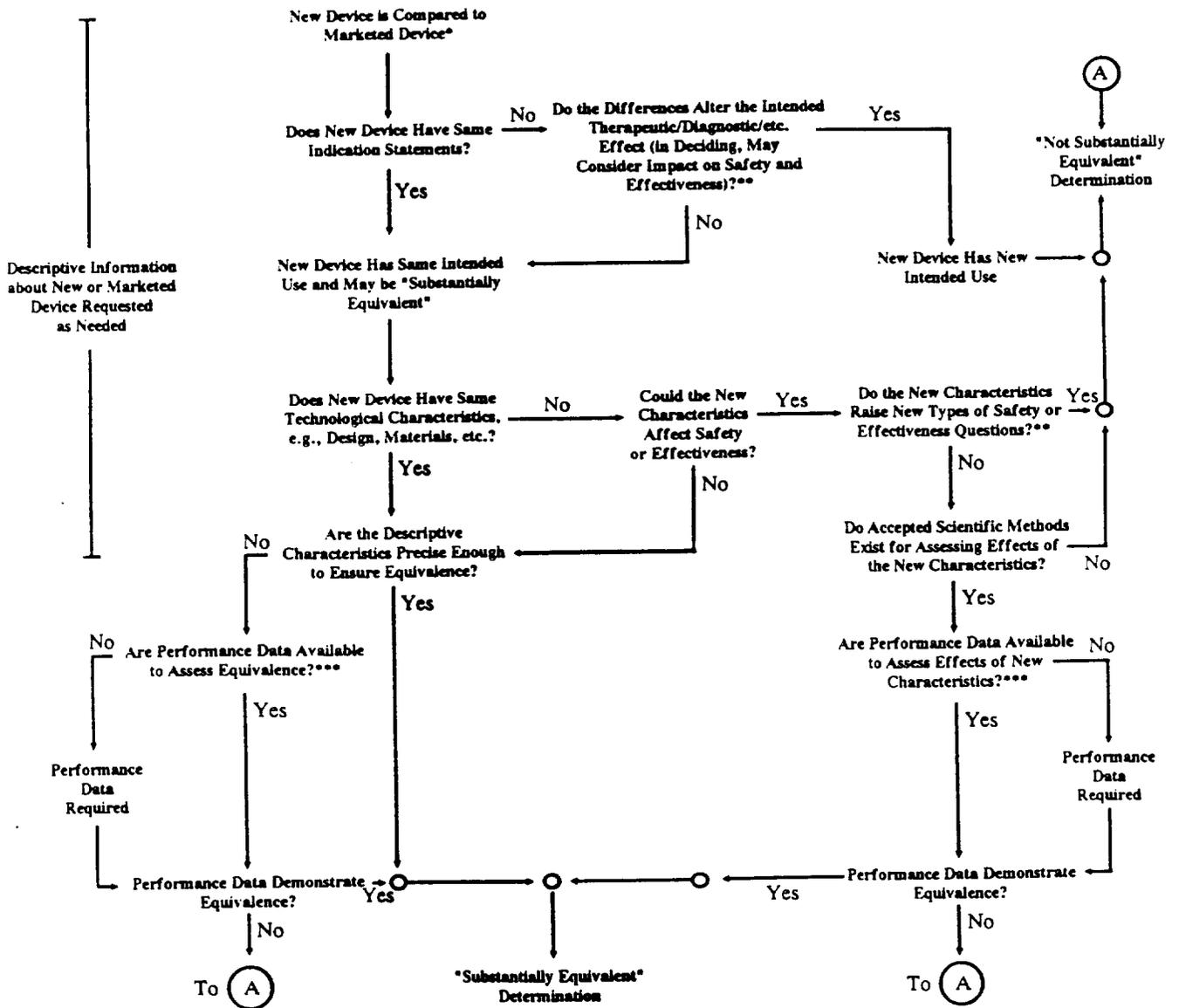
In summary, the proposed Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent in intended use, design, and material to Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas legally marketed by Wiltek Medical, Inc., American Endoscopy, Inc., and Microvasive, Inc.

61

Exhibit 4.2
510(k) "Substantial Equivalence"
Decision-Making Process

A small, handwritten mark or signature located in the bottom right corner of the page.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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52

64

SECTION 5.0

PRODUCT LABELING

- 5.1 Draft Unit Label
- 5.2 Draft Information for Use
- 5.3 Proposed Product Brochure



5.0 **PRODUCT LABELING**

5.1 **Draft Unit Label**

Included on the following pages are draft labels for the Bard® BILISYSTEM™ ERCP Cannula pouch labels.

Bard® BILISYSTEM™ ERCP Cannula
Straight

67

Straight

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<h2 style="margin: 0;">Bard® ERCP Cannula Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <td style="padding: 5px;">TIP CONFIGURATION STANDARD</td> <td style="padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin: 0;">Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION STANDARD	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center; font-weight: bold; font-size: 1.2em;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 20px;"> <p style="margin: 0;">Bard ERCP Cannula Radiopaque Tip Standard Reorder # XXXXXX</p> </div>
TIP CONFIGURATION STANDARD	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<h2 style="margin: 0;">Bard® ERCP Cannula Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <td style="padding: 5px;">TIP CONFIGURATION LONG TAPER</td> <td style="padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin: 0;">Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION LONG TAPER	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center; font-weight: bold; font-size: 1.2em;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 20px;"> <p style="margin: 0;">Bard ERCP Cannula Radiopaque Tip Long Taper Reorder # XXXXXX</p> </div>
TIP CONFIGURATION LONG TAPER	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<h2 style="margin: 0;">Bard® ERCP Cannula Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <td style="padding: 5px;">TIP CONFIGURATION SHORT TAPER</td> <td style="padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin: 0;">Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION SHORT TAPER	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center; font-weight: bold; font-size: 1.2em;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 20px;"> <p style="margin: 0;">Bard ERCP Cannula Radiopaque Tip Short Taper Reorder # XXXXXX</p> </div>
TIP CONFIGURATION SHORT TAPER	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

Bard® BILISYSTEM™ ERCP Cannula
Straight
(continued)

BR

Straight
 (continued)

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<h2 style="margin: 0;">Bard® ERCP Cannula Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <td style="padding: 5px;">TIP CONFIGURATION CONE</td> <td style="padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin: 0;">Contents: 1 Unit Lot # XXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION CONE	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center; font-weight: bold; font-size: 1.2em;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 10px;"> <p style="margin: 0;">Bard ERCP Cannula Radiopaque Tip Cone Reorder # XXXXXX</p> </div>
TIP CONFIGURATION CONE	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<h2 style="margin: 0;">Bard® ERCP Cannula Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <td style="padding: 5px;">TIP CONFIGURATION ULTRA TAPER</td> <td style="padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .021"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin: 0;">Contents: 1 Unit Lot # XXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION ULTRA TAPER	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .021"	CATHETER LENGTH 200CM	<p style="text-align: center; font-weight: bold; font-size: 1.2em;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 10px;"> <p style="margin: 0;">Bard ERCP Cannula Radiopaque Tip Ultra Taper Reorder # XXXXXX</p> </div>
TIP CONFIGURATION ULTRA TAPER	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .021"	CATHETER LENGTH 200CM					

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<h2 style="margin: 0;">Bard® ERCP Cannula Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <td style="padding: 5px;">TIP CONFIGURATION NIPPLE</td> <td style="padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin: 0;">Contents: 1 Unit Lot # XXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION NIPPLE	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center; font-weight: bold; font-size: 1.2em;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 10px;"> <p style="margin: 0;">Bard ERCP Cannula Radiopaque Tip Nipple Reorder # XXXXXX</p> </div>
TIP CONFIGURATION NIPPLE	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

20

Bard® BILISYSTEM™ ERCP Cannula
Straight
(continued)

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Straight
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<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXX 510 (K)</p> <p>BARD</p>	<h2>Bard[®] ERCP Cannula Radiopaque Tip</h2>		XXXXXX Reorder No.			
	<table border="1"><tr><td>TIP CONFIGURATION BALL</td><td>CATHETER O.D. 5FR</td></tr><tr><td>GUIDEWIRE ACCEPTED .035"</td><td>CATHETER LENGTH 280CM</td></tr></table>	TIP CONFIGURATION BALL	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 280CM	<p>Contents: 1 Unit Lot # Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use</p>
TIP CONFIGURATION BALL	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 280CM					

Bard ERCP Cannula
Radiopaque Tip
Ball
Reorder # XXXXXX



Bard® BILISYSTEM™ ERCP Cannula
Pre-curved

92

Pre-Curved

<p style="font-size: small;">Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p style="font-size: x-large; font-weight: bold; margin-top: 10px;">BARD</p>	<h2 style="text-align: center;">Bard® ERCP Cannula Pre-Curved Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 50%; padding: 5px;">TIP CONFIGURATION STANDARD</td> <td style="width: 50%; padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin-top: 10px;">Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION STANDARD	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="font-size: x-large; font-weight: bold; text-align: center;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 10px;"> <p style="font-size: small;">Bard ERCP Cannula Pre-Curved Standard Reorder # XXXXXX</p> </div>
TIP CONFIGURATION STANDARD	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

<p style="font-size: small;">Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p style="font-size: x-large; font-weight: bold; margin-top: 10px;">BARD</p>	<h2 style="text-align: center;">Bard® ERCP Cannula Pre-Curved Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 50%; padding: 5px;">TIP CONFIGURATION LONG TAPER</td> <td style="width: 50%; padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin-top: 10px;">Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION LONG TAPER	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="font-size: x-large; font-weight: bold; text-align: center;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 10px;"> <p style="font-size: small;">Bard ERCP Cannula Pre-Curved Long Taper Reorder # XXXXXXX</p> </div>
TIP CONFIGURATION LONG TAPER	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

<p style="font-size: small;">Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p style="font-size: x-large; font-weight: bold; margin-top: 10px;">BARD</p>	<h2 style="text-align: center;">Bard® ERCP Cannula Pre-Curved Radiopaque Tip</h2> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 50%; padding: 5px;">TIP CONFIGURATION SHORT TAPER</td> <td style="width: 50%; padding: 5px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 5px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 5px;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="margin-top: 10px;">Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION SHORT TAPER	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="font-size: x-large; font-weight: bold; text-align: center;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center; margin-top: 10px;"> <p style="font-size: small;">Bard ERCP Cannula Pre-Curved Short Taper Reorder # XXXXXXX</p> </div>
TIP CONFIGURATION SHORT TAPER	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

74

Bard® BILISYSTEM™ ERCP Cannula
Pre-curved
(continued)

Pre-Curved
 (continued)

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<p style="text-align: center;">Bard® ERCP Cannula Pre-Curved Radiopaque Tip</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <tr> <td style="width: 50%; padding: 2px;">TIP CONFIGURATION CONE</td> <td style="width: 50%; padding: 2px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 2px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 2px;">CATHETER LENGTH 200CM</td> </tr> </table> <p>Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION CONE	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center;"> <p>Bard ERCP Cannula Pre-Curved Cone Reorder # XXXXXXX</p> </div>
TIP CONFIGURATION CONE	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<p style="text-align: center;">Bard® ERCP Cannula Pre-Curved Radiopaque Tip</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <tr> <td style="width: 50%; padding: 2px;">TIP CONFIGURATION NIPPLE</td> <td style="width: 50%; padding: 2px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 2px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 2px;">CATHETER LENGTH 200CM</td> </tr> </table> <p>Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION NIPPLE	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center;"> <p>Bard ERCP Cannula Pre-Curved Nipple Reorder # XXXXXXX</p> </div>
TIP CONFIGURATION NIPPLE	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

<p>Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p>BARD</p>	<p style="text-align: center;">Bard® ERCP Cannula Pre-Curved Radiopaque Tip</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <tr> <td style="width: 50%; padding: 2px;">TIP CONFIGURATION BALL</td> <td style="width: 50%; padding: 2px;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 2px;">GUIDEWIRE ACCEPTED .035"</td> <td style="padding: 2px;">CATHETER LENGTH 200CM</td> </tr> </table> <p>Contents: 1 Unit Lot # XXXXXXXXX Read Complete Information For Use Prior to Use Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. STERILE unless package opened or damaged Single Patient Use Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p>	TIP CONFIGURATION BALL	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM	<p style="text-align: center;">XXXXXX Reorder No.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; text-align: center;"> <p>Bard ERCP Cannula Pre-Curved Ball Reorder # XXXXXXX</p> </div>
TIP CONFIGURATION BALL	CATHETER O.D. 5FR					
GUIDEWIRE ACCEPTED .035"	CATHETER LENGTH 200CM					

Handwritten signature

Bard® BILISYSTEM™ ERCP Cannula
Pre-curved
(continued)



Pre-Curved
 (continued)

<p style="font-size: small;">Bard Interventional Products Division C.R. Bard, Inc. 200 Ames Pond Drive Tewksbury, MA 01876 1-800-826-BARD AE1XXXXXXXX 510 (K)</p> <p style="font-size: 2em; font-weight: bold; margin-top: 10px;">BARD</p>	<div style="text-align: right; font-weight: bold; font-size: 1.2em;">XXXXXX Reorder No.</div> <div style="text-align: center; font-weight: bold; font-size: 1.5em; margin-top: 10px;"> Bard® ERCP Cannula Pre-Curved Radiopaque Tip </div> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 50%; padding: 2px; font-size: small;">TIP CONFIGURATION ULTRA TAPER</td> <td style="width: 50%; padding: 2px; font-size: small;">CATHETER O.D. 5FR</td> </tr> <tr> <td style="padding: 2px; font-size: small;">GUIDEWIRE ACCEPTED .021"</td> <td style="padding: 2px; font-size: small;">CATHETER LENGTH 200CM</td> </tr> </table> <p style="font-weight: bold; margin-top: 10px;">Contents: 1 Unit Lot # XXXXXXXXX</p> <p style="font-size: small;">Read Complete Information For Use Prior to Use</p> <p style="font-size: small;">Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.</p> <p style="font-weight: bold; font-size: small;">STERILE unless package opened or damaged</p> <p style="font-weight: bold; font-size: small;">Single Patient Use</p> <p style="font-size: small;">Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.</p> <div style="border: 1px dashed black; border-radius: 15px; padding: 10px; margin-top: 10px; text-align: center; font-size: small;"> Bard ERCP Cannula Pre-Curved Ultra Taper Reorder # XXXXXX </div>	TIP CONFIGURATION ULTRA TAPER	CATHETER O.D. 5FR	GUIDEWIRE ACCEPTED .021"	CATHETER LENGTH 200CM
TIP CONFIGURATION ULTRA TAPER	CATHETER O.D. 5FR				
GUIDEWIRE ACCEPTED .021"	CATHETER LENGTH 200CM				

5.2 Draft Information for Use

Included on the following pages are draft Information for Use for the Bard® BILISYSTEM™ ERCP Cannula. Information provided for both the straight and pre-curved design are identical.





Bard® **BILISYSTEM™**
Tools for Biliary Intervention

ERCP Cannula

Information for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Single Patient Use

STERILE unless package opened or damaged

Read this document in its entirety prior to use.

BAIRD

Bard Interventional Products Division
C.R. Bard, Inc.
1-800-826-BARD

CAEXXXXXXX/XX Revised XX/94

Description:

The Bard® BILISYSTEM™ ERCP cannula consists of a single lumen PTFE catheter with a radiopaque tip. The Bard ERCP cannula is packaged sterile and is designed for single patient use. Tip configurations include: standard, long taper, short taper, ultra taper, cone, ball and nipple.

Indications for Use:

Cannulation of the Papilla of Vater; fluoroscopic visualization of the biliary/pancreatic system.

Warnings:

- Any contrast injection into the pancreatic duct may cause pancreatitis.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Instructions for Use:

1. After removal from the shipping package, inspect the cannula for kinks, abnormal bends, flattened areas or any other damage that may have occurred during transit.

Note: Do not use if damaged.

2. Once the Papilla of Vater is endoscopically visualized, the ERCP cannula is introduced, using short deliberate movements, into the biopsy channel of the duodenoscope.

Note: A .035" guidewire may be inserted through the guidewire lumen of all cannulas except for the ultra taper tip to provide support during insertion and facilitate cannulation of the papilla.

3. Insert the tip of the cannula into the papilla.
4. Inject radiopaque contrast through the injection lumen to confirm location in the common bile duct or pancreatic duct.
5. Properly dispose of cannula.

An issued or revision date and a revision number for these instructions are included for the user's information on the first page directly beneath the telephone number of Bard Interventional Products Division. In the event that two years have elapsed between this date and product use, the user should contact Bard Interventional Products to see if additional product information is available (Telephone Number: 1-800-826-BARD).

Bard is a registered trademark of C.R. Bard, Inc. or an affiliate.
BILISYSTEM is a trademark of C.R. Bard, Inc. or an affiliate.
©1994 C.R. Bard, Inc. All rights reserved.

5.3 Proposed Product Brochure

Included on the following pages is the draft product brochure for Bard® BILISYSTEM™ ERCP Cannula.

BILISYSTEM
ERCP Cannulas

A complete line of tip configurations, combining a radiopaque design, 5Fr PTFE sheath and .035" guidewire compatibility.

- *Bard's exclusive pre-curved design provides the proper orientation toward the common bile duct for easier cannulation.*
- *A greater variety of tip configurations—available in both straight and pre-curved—permits added procedural flexibility to cannulate even the most difficult anatomy.*
- *Platinum or metal radiopaque tips assure optimum fluoroscopic visualization of the cannula tip location for added procedural confidence.*

6

B

SECTION 6.0

510(k) SUMMARY FOR THE
BARD® BILISYSTEM™ ERCP CANNULA

6.1 General Information

6.2 Summary of Similarities and Differences

6.3 Substantial Equivalence Decision Tree

84

6.0 510(k) SUMMARY FOR THE BARD® BILISYSTEM™ ERCP CANNULA

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, an adequate summary of any information respecting safety and effectiveness follows.

6.1 General Information

Name and address of submitter:

Bard Interventional Products Division
C. R. Bard, Inc.
200 Ames Pond Drive
Tewksbury, MA 01876

Contact:

John A. DeLucia
Director, Quality Assurance and Regulatory
Affairs

Date of Summary:

February 13, 1995

Name of Device:

Bard® BILISYSTEM™ ERCP Cannula



Predicate Devices:

- Wiltek E.R.C.P. Catheter (78FGE)
Wiltek Medical, Inc.
Rural Hall, NC 27045
K894867
- E.R.C.P. Cannula (78KOG)
American Endoscopy, Inc. (acquired by C.R.
Bard in 1986)
Mentor, OH 44060
K820431A
- FluoroTip™ ERCP Cannula (78KOG)
Microvasive, Inc. (Boston Scientific,
Inc.)
Watertown, MA 02172
K833417 (unable to supply a copy of
510(k))

Description and Intended Use of Device:

The 5 Fr Bard® BILISYSTEM™ ERCP Cannula is intended for cannulation of the hepatopancreatic ampulla (Papilla of Vater) for fluoroscopic visualization of the biliary/ pancreatic system. It is placed under direct vision using a side-viewing duodenoscope under fluoroscopic control. Both the straight and precurved cannula designs are provided, one per pouch, with stylet. A variety of tip designs are available. The 5 Fr outer diameter allows passage through the working channel of the endoscope, while the lumen is compatible with a 0.035 inch O.D. guidewire for

all cannula designs except the ultra taper tip configuration which is compatible with a 0.021 inch O.D. guidewire.

6.2 **Summary of Similarities and Differences**

Please refer to Exhibit 6.2 for a Table of Similarities and Differences between the Bard® BILISYSTEM™ ERCP Cannula and legally marketed devices.

Exhibit 6.2

Table of Similarities and Differences

Product Characteristic	Bard® BILISYSTEM™ ERCP Cannula	Wiltek ERCP Catheter K894867	E.R.C.P. Cannula American Endoscopy K820431A	FluoroTip™ Microvasive, Inc. K833417
Intended Use	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system	Cannulation of the Papilla of Vater for fluoroscopic visualization of the biliary/pancreatic system
Straight Cannula	yes	yes	no	yes
Curved Cannula	yes	yes	yes	yes
Available tips	Standard	Standard	Standard	Standard
	Long taper	Long taper	no	no
	Short taper	Short taper	Short taper	Short taper
	Ultra Taper	no	Ultra taper	Ultra taper
	Nipple	Nipple	Nipple	no
	Ball	Ball	no	Metal (unknown type)
	Cone	Cone	no	Metal (unknown type)
Visual Markers	yes	yes	yes	yes
Radiopaque	yes - all tips	yes - all tips	no	Standard, Short taper, Ultra taper, and Metal tip
Working Length	200 cm	200 cm	200 cm	210 cm
Cannula Diameter	5 Fr	5 Fr	5.5 Fr	5 Fr - Standard and Long taper tip 5.5 Fr - Standard, Short taper, and Ball tip
Sterile	yes	yes	no	yes
Reusable	no	no	yes	no
Compatible with 0.035 inch O.D. Guidewire	yes - except Ultra taper tip is compatible with 0.021 inch O.D.	yes	Standard tip only Short and nipple tapers 0.025 inch O.D. Ultra taper 0.018 inch O.D.	yes - all except Ultra taper which is compatible with 0.025 inch O.D.
Material (tubing)	PTFE	PTFE	PTFE	PTFE
Material (luer fitting)	Polycarbonate	Polycarbonate	Nylon	unknown
Styilet	yes	yes	yes	yes



The basic product design of the Bard® BILISYSTEM™ ERCP Cannula is similar to legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. All products share the same intended use, the cannulation of the hepatopancreatic ampulla (Papilla of Vater) for fluoroscopic visualization of the biliary/pancreatic system. All are placed under direct vision using a side-viewing duodenoscope and with fluoroscopic control.

All are manufactured of PTFE and all, except the American Endoscopy predicate device, have radiopacity (metal tip or radiopaque metal markers) to allow for confirmation of device position by X-ray. All provide visual markers at the distal tip to allow assessment of the depth of insertion relative to the cannula tip.

Wiltek and Microvasive cannulas are provided in the straight and curved designs; American Endoscopy predicate device is provided in precurved design. All specified tubes are provided with a variety of tip configurations, as shown in the previous table.

All currently marketed cannulas are provided as 5 Fr. except the American Endoscopy predicate device.

All cannulas are provided in comparable lengths.

All Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas are provided with stylets.

Although there may be minor differences in device manufacture and packaging, the proposed Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. Any difference between products raises no issue of safety and effectiveness.

6.3 Substantial Equivalence Decision Tree

The 510(k) "Substantial Equivalence" Decision-making Process (Detailed) in ODE Guidance #K86-3, Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence. Please refer to Exhibit 6.3 for a diagram of the 510(k) Decision Tree. The answers to the questions lead to a determination of substantial equivalence.

1. Does the new device have the same indication statement?

Yes. The Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas with respect to intended use. It is intended for cannulation of the hepatopancreatic ampulla (Papilla of Vater) for fluoroscopic visualization of the biliary/pancreatic system.

2. Does the new device have the same technological characteristics, e.g. design, materials, etc.?

Yes. The Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas with respect to technological characteristics (design, materials, etc.). All consist of a proximal luer adaptor, tubing, and a variety of tip shapes. Straight and precurved cannula designs are available.

All tubes are manufactured of PTFE tubing with various materials used for connectors. Materials for the Bard® BILISYSTEM™ ERCP Cannula have been shown to be nontoxic and biocompatible.

3. Are the descriptive characteristics precise enough to ensure equivalence?

Yes. A comparison of the key properties of intended use, design and materials are presented in the "Table of Similarities and Differences," Exhibit 6.2. This table compares the Bard® BILISYSTEM™ ERCP Cannula to legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. The table has been developed to support the determination that the proposed Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent to those legally marketed products.

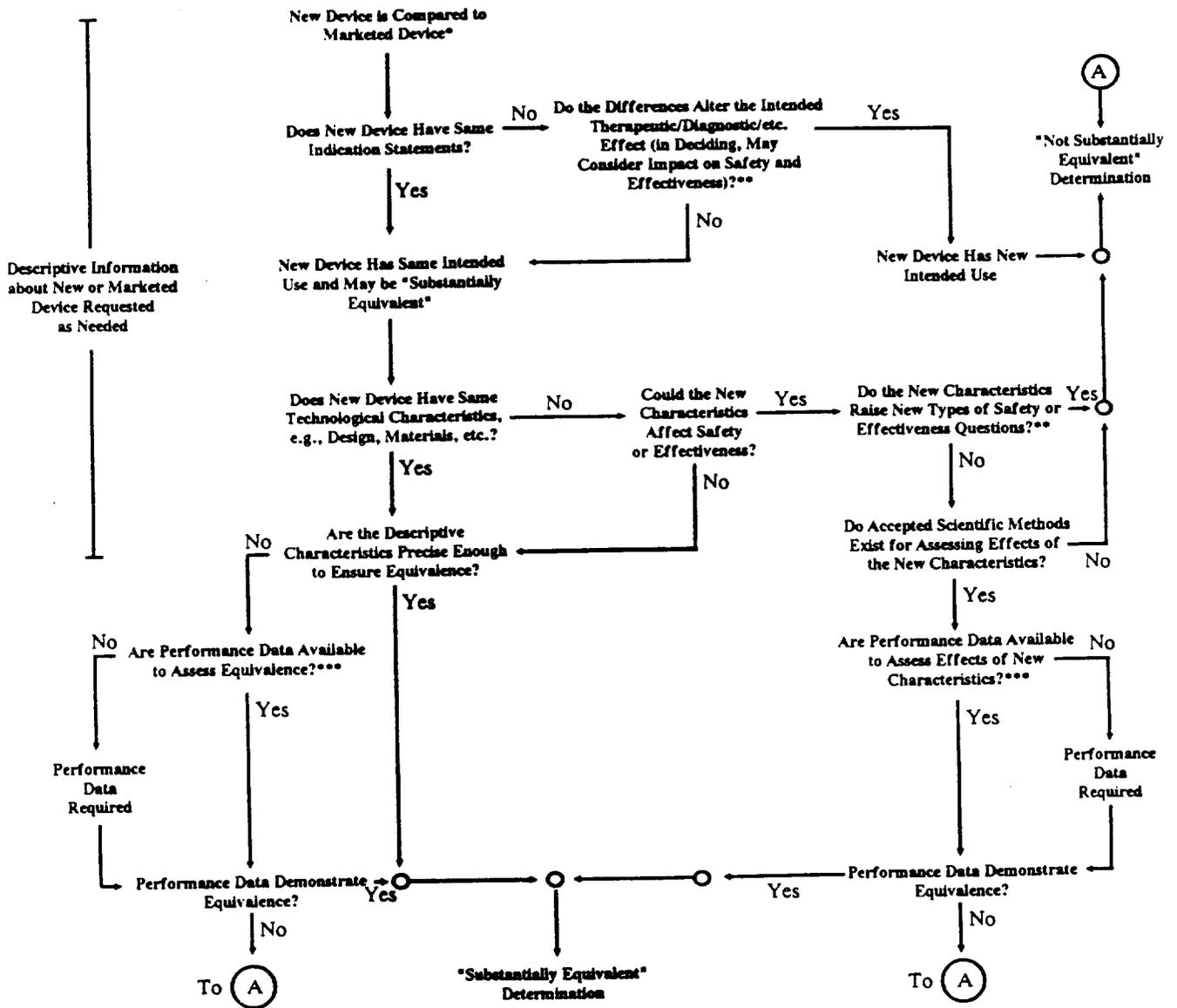
In summary, the proposed Bard® BILISYSTEM™ ERCP Cannula is substantially equivalent in intended

use, design, and material to Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas legally marketed by Wiltek Medical, Inc., American Endoscopy, Inc., and Microvasive, Inc., as discussed.

Exhibit 6.3
510(k) "Substantial Equivalence"
Decision Tree

22

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

APP-A

24

APPENDIX A

BENCH TESTING

26

BENCH TESTING

The Bard® BILISYSTEM™ ERCP Cannula and stylet were evaluated for bond tensile to demonstrate satisfactory bond strength between subassemblies. Testing was conducted on finished devices which had been subjected to a standard sterilization cycle, using generally recognized tests. The test data is attached.

APP. B

102

APPENDIX B

BIOCOMPATIBILITY TESTS

10/1

App. C

APPENDIX C

PREDICATE DEVICE INFORMATION

120

PREDICATE DEVICE INFORMATION

Section 4 Statement of Substantial Equivalence contains the discussion of equivalence of the Bard® BILISYSTEM™ ERCP Cannula to other legally marketed Endoscopic Retrograde Cholangiopancreatography (ERCP) cannulas. Product information, obtained from product catalogs and brochures, for the following predicate devices is provided in support of the assessment of substantial equivalence:

- Wiltek E.R.C.P. Catheter (78FGE)
Wiltek Medical, Inc.
Rural Hall, NC 27045
K894867
- E.R.C.P. Cannula (78KOG)
American Endoscopy, Inc. (acquired by C.R. Bard in 1986)
Mentor, OH 44060
K820431A
- FluoroTip™ ERCP Cannula (78KOG)
Microvasive, Inc. (Boston Scientific, Inc.)
Watertown, MA 02172
K833417 (unable to supply copy of 510(k))

Wiltek E.R.C.P. Catheter (78FGE)

Wiltek Medical, Inc.

K894867

128



DEC 21 1989

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850Mr. Jon S. Wilson
President
Wiltek Medical, Inc.
P.O. Box 11946
Winston-Salem, North Carolina 27116Re: K894867
Wiltek E.R.C.P. Catheter
Dated: Undated
Received: July 31, 1989
Regulatory Class: II

Dear Mr. Wilson:

RECEIVED DEC 23 1989

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Pre-market 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968 such as the requirement to submit an initial report prior to marketing radiation emitting devices, or other applicable Federal laws or regulations.

This letter immediately will allow you to begin marketing your device if you have met all other requirements described above. An FDA finding of substantial equivalence of your device to a pre-Amendment device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Halyna P. Breslawec, Ph.D.
DirectorDivision of Gastroenterology-Urology
and General Use Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

071

123

**FOOD AND DRUG ADMINISTRATION
510(K) NOTIFICATION**

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER (HFZ-401)
8757 GEORGIA AVENUE
SILVER SPRING MARYLAND 20910**

ATTENTION DOCUMENT CONTROL CLERK

THIS IS TO NOTIFY YOU THAT WILTEK MEDICAL INC. INTENDS TO MANUFACTURE AND MARKET THE FOLLOWING DEVICE. THIS NOTIFICATION IS MADE AS REQUIRED BY 21 CFR 807.87.

DEVICE NAME: BILIARY CATHETER (GASTRO/UROLOGY) 78 FGE

TRADE NAME: E.R.C.P. CATHETER

PROPRIETARY NAME: WILTEK E.R.C.P. CATHETER

ESTABLISHMENT REGISTRATION NUMBER: PENDING

CLASS OF DEVICE: CLASS TWO

NO PERFORMANCE STANDARDS HAVE BEEN ESTABLISHED FOR THIS DEVICE

PROPOSED LABELING: EXHIBIT #1

THE WILTEK MEDICAL INC. E.R.C.P. CATHETER IS SUBSTANTIALY EQUIVALANT TO THE WILSON-COOK MEDICAL INC. E.R.C.P. CATHETER IN ALL ASPECTS INCLUDING DESIGN, MATERIALS USED AND SIZES. BOTH DEVICES ARE INTENDED TO BE USED FOR ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY.

WILTEK MEDICAL INC. DATA SHEET: EXHIBIT #2

WILSON-COOK MEDICAL INC. DATA SHEET: EXHIBIT #3

**EXHIBIT #1
PROPOSED LABELING
WILTEK MEDICAL INC.**

WILTEK MEDICAL INC.

P.O. BOX 11946 WINSTON-SALEM NC 27116

E.R.C.P. CATHETER-STANDARD

**REORDER NUMBER: EC-10010
5 FR., 200 CM, STANDARD TIP, .035 WIRE GUIDE**

STERILE DATE:

N/A

LOT NUMBER:

N/A

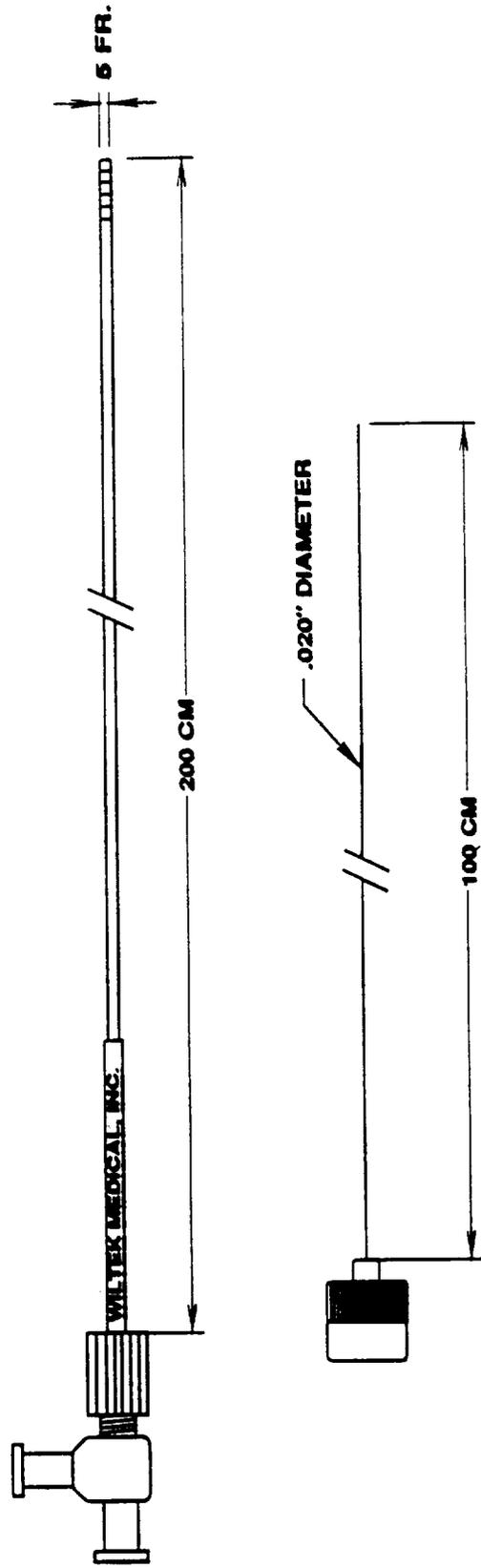
**CAUTION: FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO USE BY
OR AT THE DIRECTION OF A PHYSICIAN.**

MADE IN U.S.A.

DB

**EXHIBIT #2
WILTEK DATA SHEET**

129



MATERIALS - TABLE

FITTINGS - POLYCARBONATE
CATHETER - PTFE
STYLET WIRE - 304 S.S.

WILTEK MEDICAL INC.	TITLE: ERCP CATHETER STANDARD
DATE: 7/13/89	DRN.#: EC-10010
SCALE: NTS	DRN.BY: KTC
MATERIAL: SEE TABLE	CHK'D BY: JSW

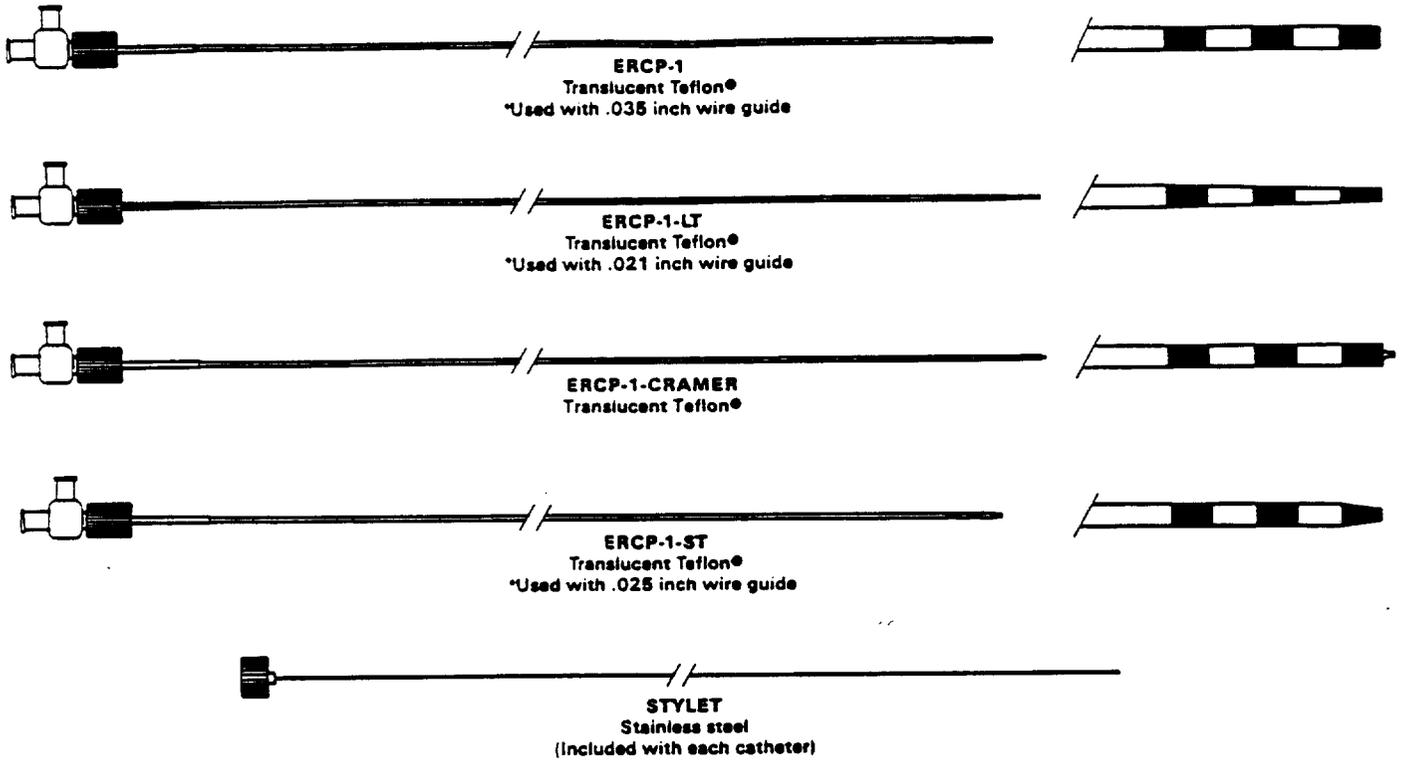
JSW

**EXHIBIT #3
WILSON-COOK DATA SHEET**

109

E.R.C.P. CATHETERS

Used for cannulation of common bile and pancreatic ducts. All catheters have three, 3 mm etched markings at the distal tip and a double female 90° side-arm Luer lock fitting. Supplied sterile in peel-open packages.



ORDER NUMBER	CATHETER		STYLET		Remarks
	French Size	Length	Tip	Length	
ERCP-1	5.0	200 cm	Slightly beveled	100 cm	*For procedures requiring wire guides
ERCP-1-LT	5.0	200 cm	Distal 12 mm tapered to 3.5 French	100 cm	For stenotic papilla
ERCP-1-CRAMER	5.0	200 cm	Distal 1 mm 23 gage metal cannula	100 cm	For minor papilla
ERCP-1-ST	5.0	200 cm	Distal 3 mm tapered to 3.5 French	100 cm	Short taper

*Wire guide available separately.

180

EXHIBIT #4
TECHNICAL COMPARISON

131

TECHNICAL COMPARISON : E.R.C.P. CATHETER

MATERIAL	WILTEK MEDICAL INC.	WILSON-COOK
CATHETER	PTFE TEFLON	PTFE TEFLON
FITTINGS	POLYCARBONATE	NYLON
STYLET WIRE	304 STAINLESS STEEL	304 STAINLESS STEEL
SIZE	5 FRENCH	5 FRENCH

VB

E.R.C.P. Cannula (78KOG)
American Endoscopy, Inc.
K820431A

1009



APR - 9 1982

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Mr. Marlin E. Younker
President
American Endoscopy, Inc.
7150 Hart Street
Mentor, Ohio 44060

Ref: K820431 A - E.R.C.P. Cannula

Dear Mr. Younker:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Standards) or class III (Pre-market Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the FEDERAL REGISTER. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the FEDERAL REGISTER will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely,

Robert G. Britain
Acting Associate Director
for Device Evaluation
Bureau of Medical Devices

077

AMERICAN ENDOSCOPY, INC.
7150 Hart Street
Mentor, Ohio 44060

January 7, 1982

Food and Drug Administration
Bureau of Medical Devices
HFK-20
8757 Georgia Avenue
Silver Spring, MD 20910

RE: Section 510(k) Premarket Notification Submission

Gentlemen:

Pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, this submission is notification of American Endoscopy's intent to market E.R.C.P. Cannulas that are substantially equivalent* to products that are on the market today.

Our submittal for Premarket Notification is enclosed. Please contact the undersigned if there is anything more you require.

Sincerely,

AMERICAN ENDOSCOPY, INC.


Marlin E. Younker
President

:cs

Enc.

* The term "substantially equivalent" as used above is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing whatever on the resolution of patent infringement suits or any other patent matter.

078

120

INDEX

	<u>Page(s)</u>
General Information on American Endoscopy, Inc.	3
Description of E.R.C.P. Cannulas	4
Substantially Equivalent Products	5, 6, 7, 8
Literature for American Endoscopy E.R.C.P. Cannulas	9
Labeling	10

079

Company:

American Endoscopy, Inc.
7150 Hart Street
Mentor, Ohio 44060
Telephone: 216-255-1698

Official Correspondent:

Marlin E. Younker
President

Owner Identification Number:

~~Applied for~~ 34-1352964

Establishment Registration Number:

Applied for

Product for Premarket Notification:

ERCP Cannula

Product Class:

Endoscopic Instruments
and accessories

080

16

DESCRIPTION

American Endoscopy Endoscopic Retrograde Cholangio-Pancreatography Cannulas are to be used in conjunction with duodenoscopes to cannulate the ampulla of Vater to allow a contrast medium to be injected into the common bile duct to help locate stones under fluoroscopy.

The unit consists of a Teflon tubing sheath, stainless steel cable guidewire, and a lightweight, positive control handle with an injection adaptor. It can be sterilized by ethylene oxide gas or an approved cold soak sterilant.

American Endoscopy E.R.C.P. Cannulas are not classified under Section 513 of the Federal Food, Drug and Cosmetic Act.

American Endoscopy E.R.C.P. Cannulas are not subject to a Premarket Approval Application under Section 515 of the Federal Food, Drug and Cosmetic Act.

Also, American Endoscopy E.R.C.P. Cannulas are not subject to performance standards established under Section 514 of the Federal Food, Drug and Cosmetic Act.

081

SUBSTANTIALLY EQUIVALENT PRODUCTS

American Endoscopy E.R.C.P. Cannulas are substantially equivalent to or identical to other E.R.C.P. Cannulas on the market today.

Mill-Rose Laboratories
8141 Tyler Blvd.
Mentor, OH 44060

Fujinon Optical, Inc.
672 White Plains Road
Scarsdale, NY 10583

Olympus Corporation of America
4 Nevada Drive
New Hyde Park, NY 11042

082

VB

SPECIFICATIONS AND PRICE LIST

NO. 250

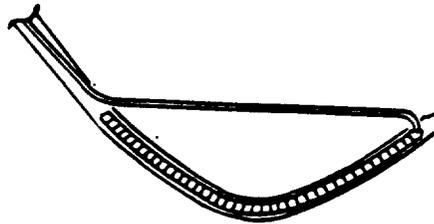
NO. 251

NO. 252



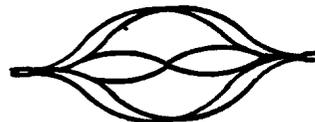
E.R.C.P. CANNULA

Product No.	Description	Working Length	Sheath Dia.	Price
#250	E.R.C.P. Cannula - Short Taper	200cm	1.6mm	\$ 24.00
#251	E.R.C.P. Cannula - Long Taper	200cm	1.6mm	\$ 24.00
#252	E.R.C.P. Cannula - Standard	200cm	1.6mm	\$ 24.00



PAPILLOTOME

Product No.	Description	Working Length	Sheath Dia.	Price
#240 Set	Includes blue handle with stop and injector preassembled to a papillotome assembly, one additional papillotome assembly and a universal active cord.	200cm	1.6mm	\$400.00
#240RA's	Replacement Papillotome Assembly (Assemblies can be custom-made to the doctor's preference)	200cm	1.6mm	\$160.00



SPIRAL BASKETS

Product No.	Description	Working Length	Sheath Dia	Price
147 Set	DUODENOSCOPE. Includes: White handle preassembled to 25 mm diameter basket assembly with Luer-lok Injection Adaptor and three replacement basket assemblies— Replacement 10 mm, 15 mm and 20 mm diameters.	200 cm	1.6 mm	\$375.00
147 RA10	Replacement 10 mm Diameter Basket Assembly with Luer-lok Injection Adaptor			100.00
147 RA15	Replacement 15 mm Diameter Basket Assembly with Luer-lok Injection Adaptor			100.00
147 RA20	Replacement 20 mm Diameter Basket Assembly with Luer-lok Injection Adaptor			100.00
147 RA25	Replacement 25 mm Diameter Basket Assembly with Luer-lok Injection Adaptor			100.00

RELATED ACCESSORIES

#124	Active Cord			\$ 24.00
#125IE	Blue Handle Assembly for Papillotomy Use			\$ 60.00
#125	White Handle Assembly (Spiral Basket Use)			\$ 45.00
#222	Universal Adaptors for Active Cord Fits Bovie, Olympus, Cameron-Miller, Wappler Pneumotome, Birtcher, Burdick, Valley Lab, CSV, NeoMed, Bantam, Martin, El Med			\$ 40.00

NOTE: When reordering, always specify handle color and product number, as handles and replacement assemblies not color matched are not interchangeable.
When ordering, always specify brand name and model of electro-surgical generator. 083



Handwritten initials

FRUITS
FUJINO OPTICAL

Cannula

Twisting Tube

Endoscopic Injector

Model No.	Description	Order No.	Olympus Equivalent	A.C.M.I. Equivalent	Order No.	Olympus Equivalent	A.C.M.I. Equivalent	Order No.	Olympus Equivalent	A.C.M.I. Equivalent
EGD-E	Gastroscope				T171800W	62306		S051600	64904	
EGD-PAN	Side/End View Scope				T171800W	62306				
EGD-SD	Duodenoscope	T172000Z	62041	9117						
Colon-L2	Colonoscope 1836mm				T172600W	62303				
Colon-M2	Colonoscope 1340mm				T172000W	62302				
Colon-S2	Colonoscope 1110mm				T172000W	62302				
SG-E	Sigmoidoscope				T171300W			S051000	64904	
BR-E	Bronchoscope	T171300Z	62821							
CH-E	Choledochoscope	T170800Z								



Cytology Brush

Channel Cleaning Brush

Model No.	Description	Order No.	Olympus Equivalent	A.C.M.I. Equivalent	Order No.	Olympus Equivalent	A.C.M.I. Equivalent
EGD-E	Gastroscope	H241600S	62107		H241600W	62206	
EGD-PAN	Side/End View Scope	H241600S	62107		H241600W	62201	
EGD-SD	Duodenoscope	H241600S	62102		H241600W	62201	
Colon-L2	Colonoscope 1836mm	H352400S	62106		H352300W	62204	
Colon-M2	Colonoscope 1340mm	H351800S	62104		H351700W	62202	
Colon-S2	Colonoscope 1110mm	H351800S	62104		H351700W	62202	
SG-E	Sigmoidoscope	H331160S			H351460W		
BR-E	Bronchoscope	H241000S			H241000W	62203	
CH-E	Choledochoscope				H360700W	62211	

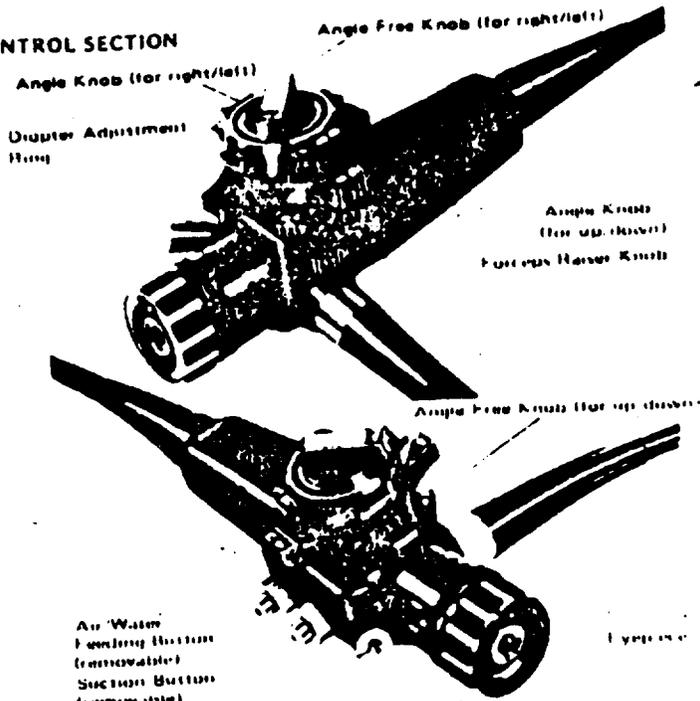


*Standard Accessories for Fujinon Fiberscopes
**For necessary attachments, see page 6
Prices FOB Scarsdale, N.Y.
Prices are subject to change without notice

08

Field of view	64°
Observation method	Side viewing
Working distance	5-60 mm, fixed focus
Light guide system	Light guide system
Outer diameter	11 mm
Inner diameter	17 mm
Bending angle (4 way)	250° (100° up, 120° down); 180° (90° right, 90° left)
Inner diameter	4.3 mm
Outer diameter	10.5 mm
Inner diameter	At 50 mm intervals between 400-1,200 mm from tip
Flexibility	In 2 steps, more flexible at tip
Minimum visible distance	1,370 mm 1,520 mm
Notes	10 mm from distal end Olympus medical camera performs automatic exposure linked with light supply.

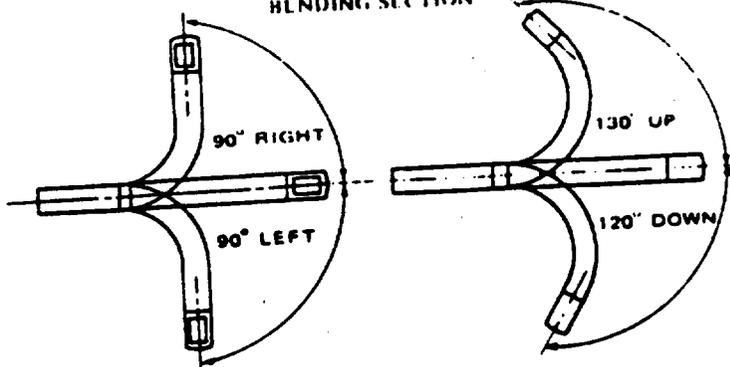
CONTROL SECTION



QUANTITY

.....	1
.....	2
.....	3
.....	1
.....	2
.....	1
.....	1
.....	1
.....	2
.....	1
.....	1

BENDING SECTION

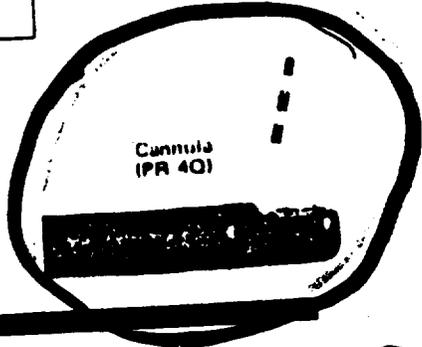
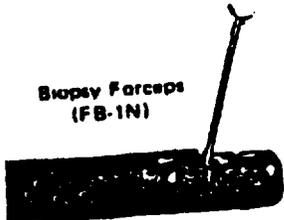


DISTAL END

- Light Guide**
Brilliant cold light is emitted for observation and photography.
- Objective Lens**
Fixed focus with depth of field 5-60 mm.
- Air/Water Feeding Port**
Air and water are emitted.



- Forceps Raiser**
Adjusts the elevation angle of the forceps, cannula, etc.
- Suction/Forceps Channel**
Used for suction of air and fluid, and for passage of biopsy forceps, cytology brush, etc.



OLYMPUS OPTICAL CO., LTD.
4-3-1, Honcho 2-chome, Shibuya-ku, Tokyo, Japan
OLYMPUS OPTICAL CO., (EUROPA) GMBH.
2, Hamburg 1, Strandstrasse 106, West Germany
OLYMPUS CORPORATION OF AMERICA
1 Nevada Drive, New Hyde Park, N.Y. 11040, U.S.A.

08

148

AMERICAN ENDOSCOPY ACCESSORY INSTRUMENTS

for the DUODENALSCOPE

Our literature is being done professionally by a printing company. Attached is a rough draft of what they are working from. It does show the selling features we will be stressing.

<p>SPIRAL BASKET</p> 	<ul style="list-style-type: none"> • SPECIAL ALLOY WIRE TO KEEP BASKETS SHAPE • COLOR CODED • KINETICALLY ENGINEERED HANDLE FOR MAXIMUM "PEEL" • REINFORCED SHEATH TO PREVENT "KINKING" • AUTOCLAVABLE • INJECTABLE 	<ul style="list-style-type: none"> • #177, 200cm LONG, 1.6mm
<p>ERCP CANNULAS</p> 	<ul style="list-style-type: none"> • CONTRAST MEDIA INJECTION CAPABILITY • PRE-MARKED • WITH OR WITHOUT TAPERED TIP • CONTROL HANDLE TO MINIMIZE FATIGUE • STERILIZED BY ETO OR COLD STERILANT 	<ul style="list-style-type: none"> • #XX - SHORT TAPERED TIP • #XX - LONG TAPERED TIP • #XX - NO TAPER
<p>PAPILLOTOMES</p> 	<ul style="list-style-type: none"> • CONTRAST MEDIA INJECTION CAPABILITY • LIGHTWEIGHT, POSITIVE CONTROL HANDLE • ALL PLASTIC HANDLE ELIMINATES SHOCKS • AUTOCLAVABLE • LENGTH OF CAUTERY WIRE CHANGEABLE • SPECIAL ALLOY CAUTERY WIRE TO HELP ELIMINATE FRAYING 	<ul style="list-style-type: none"> • #XX - 200cm LONG, 21

AMERICAN ENDOSCOPY, INC
7150 MARKET STREET

ASB

AMERICAN ENDOSCOPY, INC.
7150 Hart Street
Mentor, Ohio 44060

INSTRUCTION SHEET FOR ERCP CANNULA

After opening the package, carefully inspect the cannula for any kinks, bends or flat spots that may have occurred during transit. Unwind the cannula and inspect the distal end that is pre-curved. It can be shaped more by manual shaping by hand. Introduce the cannula into the biopsy valve with short strokes as to eliminate potential bending during insertion. Some endoscopists prefer to load the ERCP Cannula into the endoscope and check its proper curve coming out of the distal end of the duodenoscope prior to insertion of the endoscope into the patient. If this procedure is followed, the endoscopist can possibly shape the curve even more during the setup procedure. If you prefer to insert the cannula after the endoscope has been located in the patient, the natural curve or cast of the cannula will consistently allow the distal end of the cannula to exit out of the distal end of the endoscope with the proper angle needed for cannulation.

Adequate rinsing of the cannula is necessary to completely remove any remaining water soluble contrast media. The stylet should be removed and thoroughly flushed of contrast media. Scrupulous mechanical cleaning after each use, using a surgical detergent is imperative. An ultrasonic cleaner may be used to help remove particulate matter. After mechanical cleaning, the handle can be disinfected with certain iodophors or glutaraldehyde. Follow the manufacturer's recommendations for use. Adequate rinsing is necessary to prevent possible residual toxic effects. The cannula can be sterilized by ethylene oxide gas or cold sterilant.

Shipped non-sterile and recommended for single use only.

087



AMERICAN ENDOSCOPY INC.

7150 HART STREET • MENTOR, OHIO 44060 • TELEPHONE (216) 255-1698

March 24, 1982

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, MD 20910

Gentlemen:

Ref: K820431 E.R.C.P. Cannula

Additional information requested by the Agency for the above referenced medical device was for an engineering sketch, specifications and a sample label for packaging.

Enclosed herein is our engineering sketch showing specifications and a sample of the labeling for packaging.

I trust this will meet your requirements, but if more information is required, I will be happy to supply it. Thank you.

Sincerely,

AMERICAN ENDOSCOPY, INC.

Marlin E. Younker/jcs

Marlin E. Younker
President

:cs

Enc.

088

A handwritten signature or initials, possibly 'WJ', located in the bottom right corner of the page.

March 3, 1982

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

MAR 8 1982

Ref: K820431 E.R.C.P. Cannulas

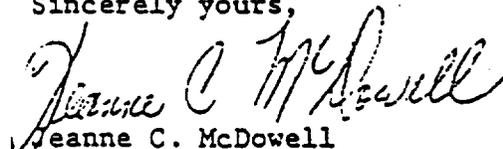
American Endoscopy, Inc.
Att: Marlin E. Uounger
7150 Hart Street
Mentor, Ohio 44060

We are holding your above-referenced 510(k) submission for 30 days pending receipt of additional information that was requested by this Agency. This information should be submitted in duplicate to:

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, MD 20910

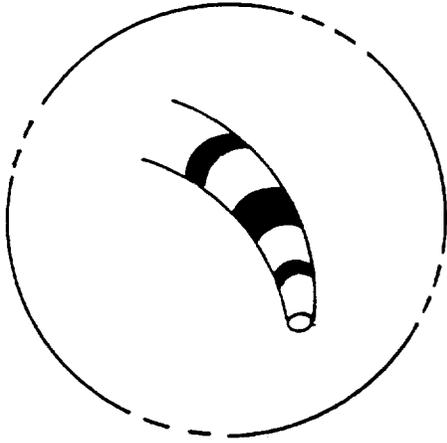
If after 30 days the requested information is not received, your submission will be deleted from our system and returned to you. If you then wish to resubmit this 510(k) notification, a new number will be assigned and acknowledged upon receipt, and the 90-day time period will begin again.

Sincerely yours,

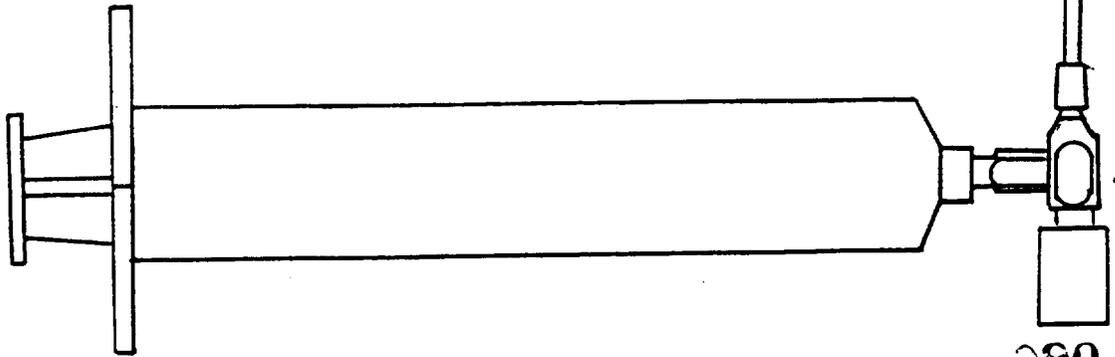
Jeanne C. McDowell
ChiefDocument Control Center
Bureau of Medical Devices

089





Catheter: TFE Teflon 1/8" O.D. x 1/16" I.D.
OAL - 100"



Tee Luer Hub
#66 Nylon

390

Handwritten initials or a signature in the bottom right corner of the page.

LABELING

On the following page is a sample of what the labeling will be like for our E.R.C.P. Cannulas.

The E.R.C.P. Cannulas will be slightly coiled to fit into a 2-mil clear poly bag printed as shown. The lettering will be blue and the space inside the rectangle will be white. The lot number will be stamped on the bottom of the package and each bag will receive a printed product identification label as shown.

This sample is a mark-up of what the real bags will look like when we receive them from the vendor. Naturally, the printing will look more professional than what is included herein.

We consider our "Instructions for Use" as part of the labeling and they will be enclosed in each individual bag. A copy of the "Instructions for Use" is included in the original 510(k).



#E18100

E.R.C.P. Cannula

NON-STERILE

NOTICE: Federal law (U.S.A.) restricts this device
to use by or on the order of a physician.

INSTRUCTIONS FOR USE INCLUDED IN PKG.



AMERICAN ENDOSCOPY INC.
7150 HART STREET • MENTOR OHIO 44060

Lot Number

1988/



1988

033

49

Device Labeling E.R.C.P. Cannula
Wiltek Medical, Inc.
American Endoscopy, Inc.
Microvasive, Inc.

093

RD

Wiltek Medical, Inc.

Price List 1992

151

SUPPLEMENTARY PRICE LIST effective 5/1/92

CATALOG NO.	DESCRIPTION	TIPS	PRICE
ERCP CATHETERS WITH RADIOPAQUE MARKERS			
EC-10010	5 FRENCH (1.66 MM) - 200 CM	STANDARD	PLATINUM \$30.00
EC-10020	5 FRENCH (1.66 MM) - 200 CM	LONG TAPER	PLATINUM \$30.00
EC-10030	5 FRENCH (1.66 MM) - 200 CM	SHORT TAPER	PLATINUM \$30.00
EC-10040	5 FRENCH (1.66 MM) - 200 CM	BALL TIP	STAINLESS STEEL \$35.00
EC-10060	5 FRENCH (1.66 MM) - 200 CM	CONE TIP	STAINLESS STEEL \$35.00
EC-10080	5 FRENCH (1.66 MM) - 200 CM	NIPPLE TIP	PLATINUM \$30.00

ERCP CATHETERS PRECURVED WITH RADIOPAQUE MARKERS			
EC-10010-G7	5 FRENCH (1.66 MM) - 200 CM	STANDARD	PLATINUM \$30.00
EC-10020-G7	5 FRENCH (1.66 MM) - 200 CM	LONG TAPER	PLATINUM \$30.00
EC-10030-G7	5 FRENCH (1.66 MM) - 200 CM	SHORT TAPER	PLATINUM \$30.00
EC-10040-G7	5 FRENCH (1.66 MM) - 200 CM	BALL TIP	STAINLESS STEEL \$35.00
EC-10060-G7	5 FRENCH (1.66 MM) - 200 CM	CONE TIP	STAINLESS STEEL \$35.00
EC-10080-G7	5 FRENCH (1.66 MM) - 200 CM	NIPPLE TIP	PLATINUM \$30.00

PAPILLOMATA WIRE GUIDED (WIRE GUIDE INCLUDED)			
PW-21200	5.5 FRENCH (1.8 MM) - 200 CM	15 MM CUTTING WIRE / 5 MM TIP	\$120.00
PW-21210	6.5 FRENCH (1.8 MM) - 200 CM	20 MM CUTTING WIRE / 5 MM TIP	\$120.00
PW-21220	5.5 FRENCH (1.8 MM) - 200 CM	25 MM CUTTING WIRE / 5 MM TIP	\$120.00
PW-21230	5.5 FRENCH (1.8 MM) - 200 CM	30 MM CUTTING WIRE / 5 MM TIP	\$120.00
PW-21200-20	5.5 FRENCH (1.8 MM) - 200 CM	15 MM CUTTING WIRE / 20 MM TIP	\$120.00
PW-21210-20	6.5 FRENCH (1.8 MM) - 200 CM	20 MM CUTTING WIRE / 20 MM TIP	\$120.00
PW-21220-20	5.5 FRENCH (1.8 MM) - 200 CM	25 MM CUTTING WIRE / 20 MM TIP	\$120.00
PW-21230-20	5.5 FRENCH (1.8 MM) - 200 CM	30 MM CUTTING WIRE / 20 MM TIP	\$120.00
PW-21200-35	5.5 FRENCH (1.8 MM) - 200 CM	15 MM CUTTING WIRE / 35 MM TIP	\$120.00
PW-21210-35	6.5 FRENCH (1.8 MM) - 200 CM	20 MM CUTTING WIRE / 35 MM TIP	\$120.00
PW-21220-35	5.5 FRENCH (1.8 MM) - 200 CM	25 MM CUTTING WIRE / 35 MM TIP	\$120.00
PW-21230-35	5.5 FRENCH (1.8 MM) - 200 CM	30 MM CUTTING WIRE / 35 MM TIP	\$120.00

BALLOON STONE EXTRACTORS				
BSE-21500	5.5 FRENCH (1.84 MM)	10 MM BALLOON	.025" WIRE GUIDE	\$75.00
BSE-21810	7 FRENCH (2.3 MM)	15 MM BALLOON	.035" WIRE GUIDE	\$75.00



P.O. BOX 11946 WINSTON-SALEM NC 27116
919-969-2737 • 1-800-345-3636 • FAX 919-969-9055

094
WMI-082482

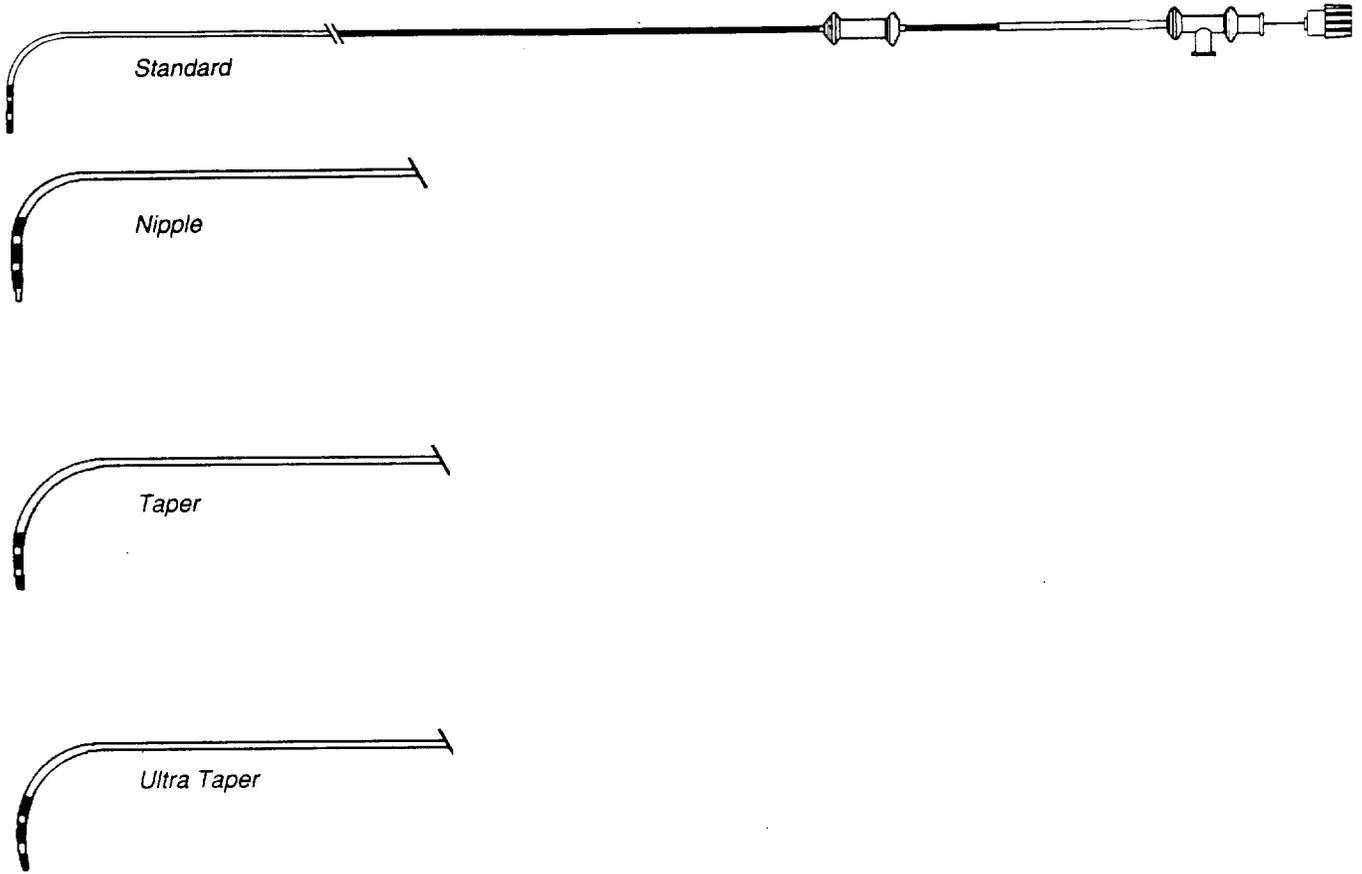
American Endoscopy, Inc.
(Acquired by C.R. Bard)

Price List 1994



Biliary Endoscopic Accessories

Bard® ERCP Cannulas
 Non-Sterile
 Non-Radiopaque
 Single Use



Catalog Number	Description	O.D. (mm)	Guidewire Accepted	Length (cm)	Unit	Price Each		
						2	4-10	12+
000155	Nipple Tip ERCP cannula and stylet	1.8	.025"	200	2/box	\$40	\$38	\$34
000156	Taper Tip ERCP cannula and stylet	1.8	.025"	200	2/box	40	38	34
000159*	Standard Tip ERCP cannula and stylet	1.8	.035"	200	2/box	40	38	34
000183	Ultra Taper Tip ERCP box	1.8	.018"	200	2/box	40	38	34

096

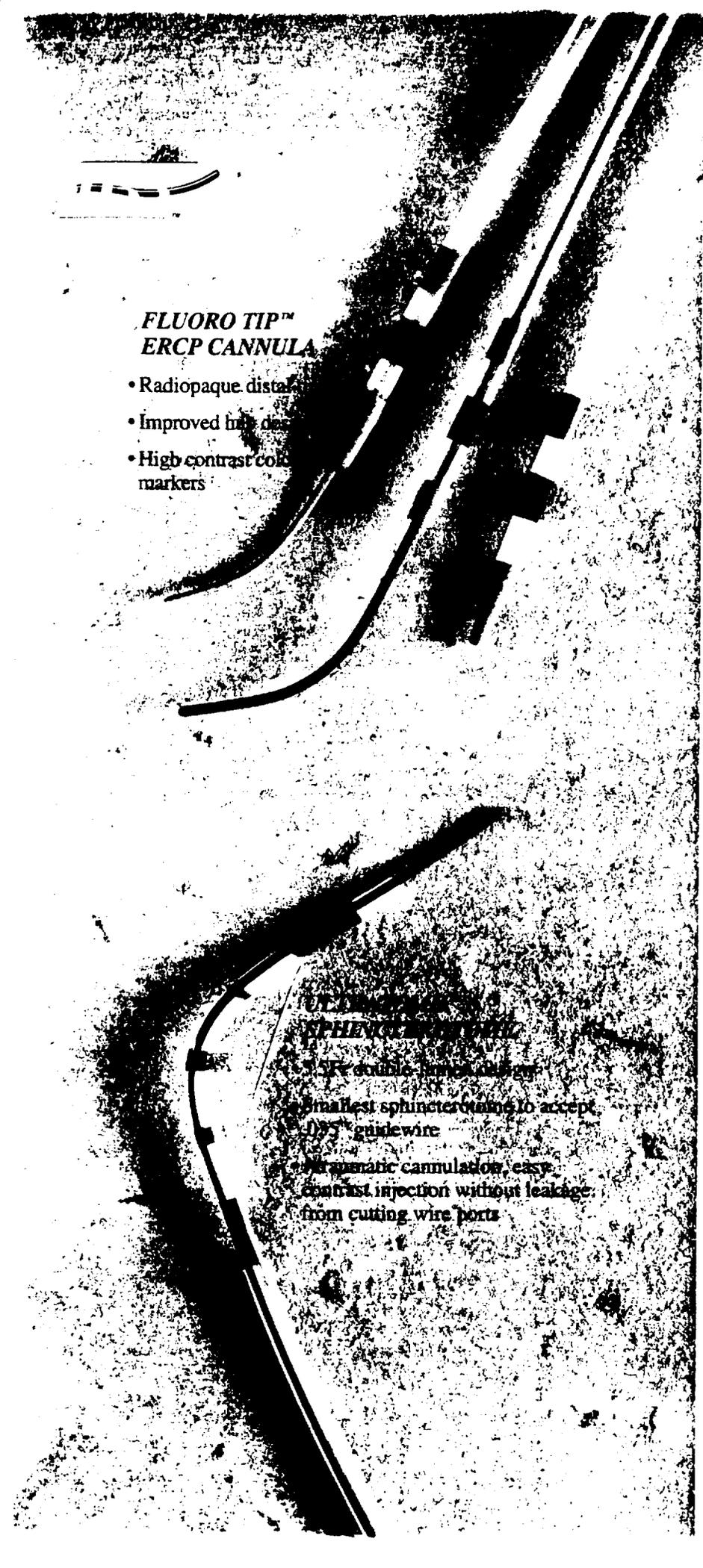
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Microvasive, Inc.
(Boston Scientific, Inc.)

Price List 1994





**FLUORO TIP™
ERCP CANNULA**

- Radiopaque distal
- Improved hub des
- High contrast col
markers

**UTERINE
SPHINCTEROMYOMY**

- 3Fr double-lumen design
- Smallest sphincterotome to accept
.035 guidewire
- Frictionless cannulation, easy
contrast injection without leakage
from cutting wire ports

• Versatility and functionality assure optimal performance for the endoscopy team...from specialized guidewires... to the smallest .035 wireguided sphincterotome...to cannulas with easily-visualized radiopaque distal markers.

• Microvasive has the array of advanced biliary devices you need today. Equally important, we're developing—with the profession—the leading-edge devices of tomorrow.



BILIARY

CANNULAS

■ FLUORO TIP SINGLE-USE ERCP CANNULAS

Order Number	Description	O.D.		Length (cm)	Recommended Guidewire (in)	Price
		(mm)	(Fr)			
3096	Fluoro Tip Standard Tip	1.7	5	210	.035	\$45 ea
3097	Fluoro Tip Tapered Tip	1.7	5	210	.035	\$45 ea
3098	Fluoro Tip Ultra Tapered Tip	1.7	5	210	.025	\$45 ea

Fluoro Tip U.S. Patent 5.256.158

■ SINGLE-USE ERCP CANNULAS

Order Number	Description	O.D.		Length (cm)	Recommended Guidewire (in)	Price
		(mm)	(Fr)			
4339	ERCP Cannula Tapered Tip	1.7	5	210	.035	\$38 ea
4340	ERCP Cannula Standard Tip	1.7	5	210	.035	\$38 ea
4341	ERCP Cannula Metal Tip	1.7	5	210	.035	\$38 ea
4342	ERCP Cannula Ultra Tapered Tip	1.7	5	210	.025	\$38 ea

157

098