

00-00072

MAR 30 1994

K940187

Summary of Safety and Effectiveness
Pursuant to Section 513 (i)
of the Food, Drug and Cosmetic Act

I. General Provisions

Common or Usual Name: Guiding Catheter

Proprietary Name: ENVOY™ Guiding Catheter

II. Name of Predicate Devices

Cordis Corporation PTCA 6F Guiding Catheter 510 (k) # K915374
Cordis 5.0 French Super Torque Catheters 510 (k) #K915836

III. Classification

Class II

IV. Performance Standards

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The ENVOY Guiding Catheters are designed for the intravascular introduction of interventional/diagnostic products in the peripheral and neurovascular system.

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the ENVOY Guiding Catheters.

VII. Summary of Substantial Equivalence

The ENVOY Guiding Catheters are similar in its basic design, construction, indication for use and performance characteristics to other commercially available infusion catheters.

K940187/A3

ORIGINAL

Codman
a Johnson & Johnson company

December 18, 2008

FDA CDRH DMC

JAN 08 2009

Received

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

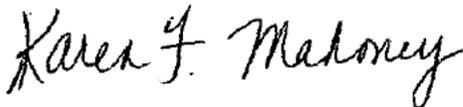
Reference: Add to File Letter
Cordis Neurovascular 510(k)s – Transfer of Ownership

Dear Sir or Madam:

The purpose of this letter is to notify FDA that effective December 29, 2008, Cordis Neurovascular Inc., will be merged with and become a business unit with Codman & Shurtleff, Inc. With this transfer, all rights of the attached 510(k)s are transferred to Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham, Massachusetts 02767. Codman acknowledges ownership of these 510(k)s.

Please feel free to contact me at 508-828-3704 or kmahoney@its.jnj.com if you should have any questions regarding this transfer of ownership.

Regards,



Karen F. Mahoney
Worldwide Director of Regulatory

ORIGINAL

K032553/A1



December 18, 2008

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Codman has supplied the attached letter acknowledging ownership of the 510(k)s.

Please feel free to contact me at 908-412-3065 or jodonne7@its.jnj.com if you should have any questions regarding this transfer of ownership.

Regards,

James P. O'Donnell
Vice President, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powderhorn Drive
Warren, New Jersey 07059

2 K39

ORIGINAL

510(k) Ownership Transferred to Codman & Shurtleff, Inc.

510(k) #	Description
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K965174	TRUFILL PVA Particles
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K070279	HYPERTRANSIT Infusion Catheter
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K930982	INSTINCT Guidewires
K943522	PROMPT Guidewires (Obsolete)
K955637	ESSENCE Guidewires
K991646	Agility (.010) Steerable Guidewires
K001033	Agility (.014) Steerable Guidewires
K010511	Agility (.016) Steerable Guidewires



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2009

James P. O'Donnell
Vice President, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powderhorn Drive
Warren, New Jersey 07059

Re: See Attached

Dear Mr. O'Donnell:

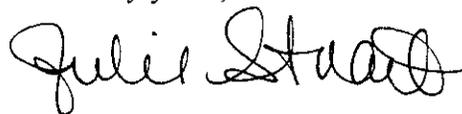
We have reviewed your letter, received January 8, 2009, stating that the rights to the above referenced premarket notification (510(k)) have been transferred. Transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitter in our database. Please note, as per 21 CFR 807.85(b), a firm may not both manufacture and distribute a device under their own name without having their own 510(k).

We suggest that information showing the transfer of the 510(k) and its current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276-0100 if you have any questions on what information we expect to be maintained in your files.

"Please note, under 21 CFR 807.81(a)(2) a firm may not both retain and transfer 510(k) marketing rights to another person, e.g., a contract manufacturer, because each person who manufactures and distributes a device must have their own 510(k), if the device is not exempt from the premarket notification requirement. Likewise, distributors need 510(k) clearances before marketing devices when they alter them by doing more than putting their name on the device, because such actions would disqualify them from the 510(k) distributor exemption under 21 CFR 807.85(b)."

If you have any other questions regarding this letter, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

A handwritten signature in black ink that reads "Julie Stuart". The signature is written in a cursive style with a large, looped "J" and "S".

Julie "Brandi" Stuart
Consumer Safety Officer
Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

CC: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

ORIGINAL

510(k) Ownership Transferred to Codman & Shurtleff, Inc.

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K010511	Agility (.016) Steerable Guidewires

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 1-8-09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K940187/A3

To: Division Director: CV/DCD/13FB

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: 2-17-09

Date:

POS

COPY

K940187/A3

Cordis

a Johnson & Johnson company

NEUROVASCULAR

December 18, 2008

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

FDA CDRH DMC

JAN 08 2009

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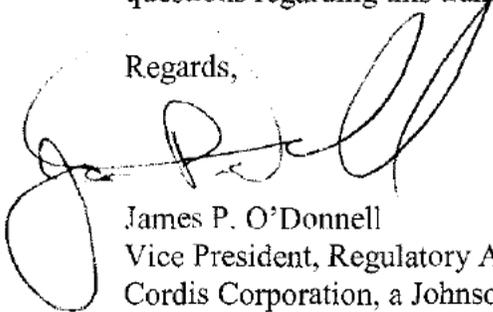
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Regards,



James P. O'Donnell
Vice President, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powderhorn Drive
Warren, New Jersey 07059

K28

COPY

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COPY



December 18, 2008

FDA CDRH DMC

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Regards,

A handwritten signature in cursive script that reads "Karen F. Mahoney".

Karen F. Mahoney
Worldwide Director of Regulatory

510(K) ROUTE SLIP

510(k) NUMBER K940187 PANEL CV DIVISION DCRND BRANCH ICDB
TRADE NAME ENVOY GUIDING CATHETER
COMMON NAME GUIDING CATHETER
PRODUCT CODE _____

DQY
SUN
IN
PA

APPLICANT CORDIS ENDOVASCULAR SYSTEMS, INC.
SHORT NAME CORDENDOSYST
CONTACT MARLENE WRIGHT
DIVISION _____
ADDRESS 14740 N.W. 60TH AVENUE
MIAMI LAKES, FL 33014
PHONE NO. (305) 824-8618 FAX NO. (305) 824-8610
MANUFACTURER CORDIS ENDOVASCULAR SYSTEMS, I REGISTRATION NO. _____

DATE ON SUBMISSION 12-JAN-94 DATE DUE TO 510(K) STAFF 29-MAR-94
DATE RECEIVED IN ODE 13-JAN-94 DATE DECISION DUE 13-APR-94
DECISION _____ DECISION DATE MAR 30 1994



MAR 30 1994

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Marlene Wright
Manager Regulatory Affairs and
Clinical Research
Cordis Endovascular Systems, Inc.
14740 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K940187
Envoy Guiding Catheter
Regulatory Class: II
Dated: January 12, 1994
Received: January 13, 1994

Dear Ms. Wright,

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 (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. 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, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. 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 on the labeling for your device, please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. 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,

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



Memorandum

Date _____

From REVIEWER(S) - NAME(S) Glenn Byrd / Lev Keely

Subject 510(k) NOTIFICATION K940187

To THE RECORD

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

- (A) Is substantially equivalent to marketed devices.
- (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:*

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

Predicate Product Code w/panel and class:

DCY II 74

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

REVIEW:

Jan A. Ryan
(BRANCH CHIEF)

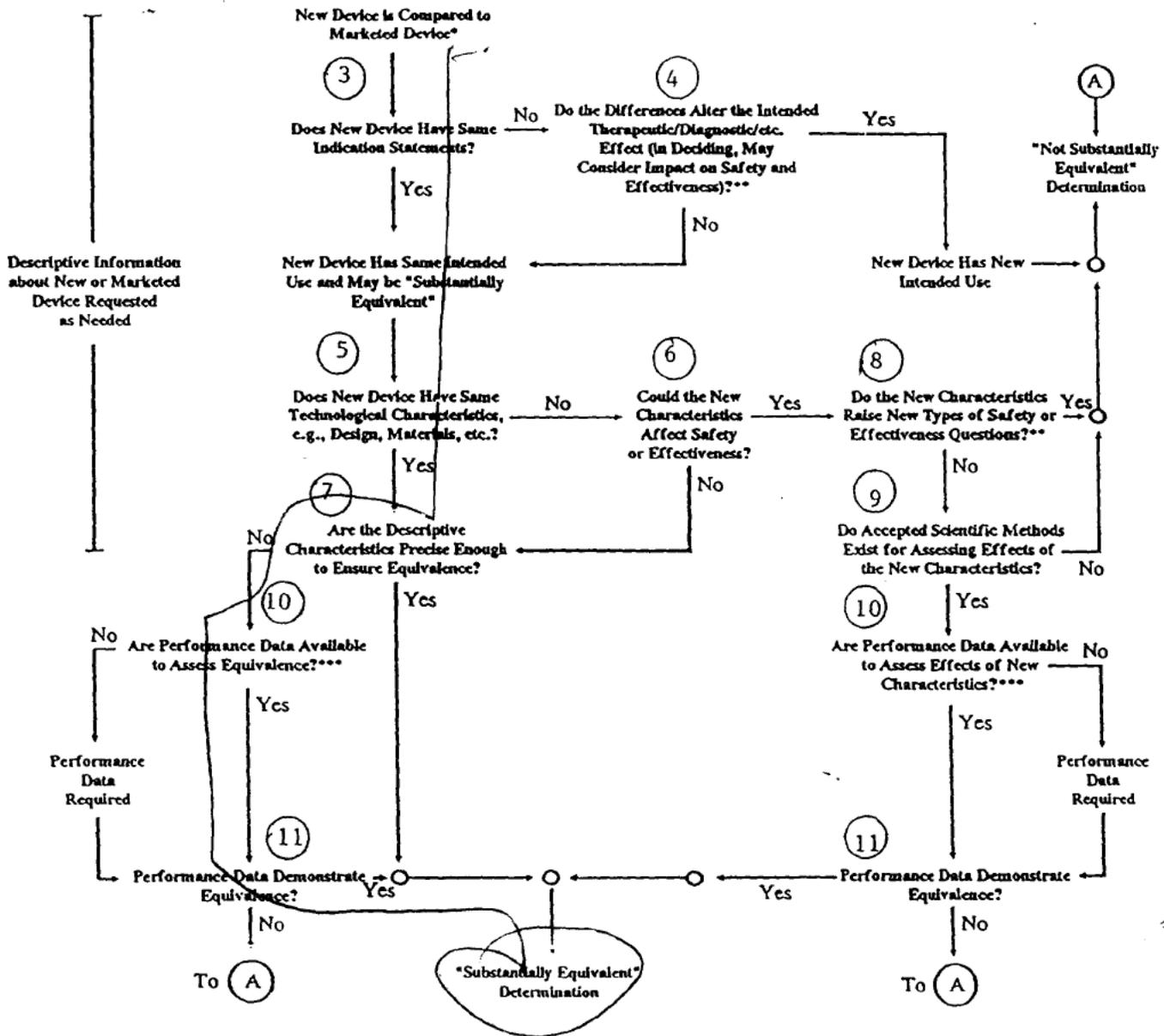
1CDB 3/28/94
BRANCH CODE (DATE)

FINAL REVIEW:

Kenneth Palmer
(DIVISION DIRECTOR)

3/30/94
(DATE)

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.

TRADE NAME: Envoy Guiding Catheter COMMON NAME: Percutaneous Catheter

PRODUCT TO WHICH COMPARED: K 915374, K915836, K914856, K914199
(510(k) NUMBER IF KNOWN)

YES	(NO)
-----	------

- 1. IS PRODUCT A DEVICE?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF NO STOP
- 2. DEVICE SUBJECT TO 510(k)?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF NO STOP
- 3. SAME INDICATION STATEMENT?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF YES GO TO 5
- 4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF YES STOP - **NE**
- 5. SAME TECHNOLOGICAL CHARACTERISTICS?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF YES GO TO 7
- 6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF YES GO TO 8
- 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?

<input type="checkbox"/>	<input checked="" type="checkbox"/>
--------------------------	-------------------------------------

 - IF NO GO TO 10
- IF YES STOP - **SE**
- 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF YES STOP - **NE**
- 9. ACCEPTED SCIENTIFIC METHODS EXIST?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF NO STOP - **NE**
- 10. PERFORMANCE DATA AVAILABLE?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF NO REQUEST DATA
- 11. DATA DEMONSTRATE EQUIVALENCE?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

SE

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

L

Glenn N. Byrd

FDA/CDRH/ODE/DCRND/ICDB

March 25, 1994

Comments on K940187 for the Envoy Guiding Catheter from
Cordis Endovascular Systems, Inc. dated January 12, 1994

This submission requests clearance to market a modified version of this sponsor's 6F coronary guiding catheter. Modifications proposed include (b)(4)

(b)(4)

Because the primary concern with this file is the proposed neurovascular indications for use, I requested a consulting review from the Neurology Branch and Lev Keely's review is attached. Since this consulting review addresses virtually all aspects of this file, I recommend that it be the primary review of this document. The file probably should have just been transferred to NEDB but that did not occur.

Consultation with Dr. Bram Zuckerman, DCRND Medical Officer, resulting in the identification of no new concerns regarding the use of this device in the peripheral circulation. Since it is virtually identical to that used in the coronary circulation, he stated that this device was moving into a less strenuous, tortuous, and critical environment - the peripheral arteries.

This model of guiding catheter will not be indicated for use in the coronary arteries.

All aspects of the device such as materials, packaging, manufacturing, sterilization, and design are identical to the current coronary file (K915374). Predicate guiding catheters with cerebral use wording in their instructions include K915836, K914856, and K914199.

No additional questions or concerns arose during our reviews. **I recommend SE.**

Glenn N. Byrd
3/25/94

Byrd
3/28/94

4

MEMORANDUM

DATE: March 4, 1994
FROM: G. Levering Keely, Neurological Devices Branch, HFZ-450
Office of Device Evaluation, DCRND
TO: Glenn Byrd, ICDB
VIA: Robert Munzner, Chief Neurology Devices Branch *RF*
SUBJECT: K940187, Cordis - Envoy Guiding Catheter

This is a review of the above referenced 510(k) for use in neurovascular indications.

This device is a guiding catheter which is utilized to access the cranial circulation in order to place a catheter for neurovascular use. It is a single use disposable device.

Description - See attachments II and III of the 510(k) submission for specific complete material listing.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Dimensions

Length - 100 cm
OD - 6 french, 0.079 inches
ID - 0.062 inches

Tip configurations - See Attachment II for diagrams

Vertebral (45° and 70°)
Cerebral Burke
Head Hunter (H₁ and H₃)
Straight

Sterilization - per AAMI guidelines by (b)(4)

Non-pyrogenic

Equivalence is being claimed based upon K915836 and K914856 and K914199. These devices, while not specifically for cerebral use, have been reviewed by Veronica Price. The labeling included wording for cerebral use.

Equivalence also based upon:

Cordis 5.0 Fr Super Torque Catheter which is smaller and more pliable in theory than the larger ENVOY guiding catheter of this submission.
Cordis 6 french PTCA Guiding Catheter.
Cordis 6 French Brite Tip catheter.
Materials for all of the above are the same.

TESTING PERFORMED

MEMORANDUM
K940187
Cordis ENVOY Catheter

March 8, 1994

=====
(b)(4)

Testing performed on the (b)(4) catheters provided a (b)(4) test when (b)(4). Testing demonstrated equivalence in all aspects of the above.

(b)(4) I testing (b)(4) (b)(4)
(b)(4)

I discussed several questions with Marlene Wright (305) 842-8600 from Cordis.

(b)(4)

It is clear that these catheters are intended for use in maneuvering through the aorta to enter the carotid artery for ultimate insertion of other catheters and they are not intended for use in and of themselves intracranially.

I recommend that this device be found SE to other similar devices for use in accessing the cranial vasculature. If you have further questions please feel free to contact me.


G. Levering Reely

2. EXPLAIN WHY NOT SUBJECT TO 510(k):

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: _____

Records processed under FOIA Request # 2015-8094; Released by CDRH on 12-10-2015

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW: _____

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED: _____

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: _____

ATTACH ADDITIONAL SUPPORTING INFORMATION

10

Premarket Notification (510(k)) Checklist for Acceptance Decision

K 940187 Date DMC Received 1/13/94

Device Trade Name: Envoy Guiding Catheter

Reason for 510(k) Device modification

Division/Branch: DCPND/ICDB

Administrative Reviewer Signature: [Signature] Date 2-10-94

Supervisory Signature: [Signature] Date 3/30/94

Did the firm request expedited review NO

Did we grant expedited review _____

X
accepted

refuse to
accept

Yes
Present
Omission Justified

No
Inadequate
Omitted

I. Critical Elements:		
A. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy? <i>NO</i>	<input type="checkbox"/>	<input type="checkbox"/>
C. Is device subject to review by CDRH?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. (i) Are you aware that this device has been the subject of a previous NSE decision? <i>NO</i> (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	<input type="checkbox"/>	<input type="checkbox"/>
E. (i) Are you aware of the submitter being the subject of an integrity investigation? <i>NO</i> If yes, consult the ODE Integrity Officer.	<input type="checkbox"/>	<input type="checkbox"/>
(ii) Has the ODE Integrity Officer given permission to proceed with the review? <i>N/A</i> (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input type="checkbox"/>

Yes
Present
Omission Justified

No
Inadequate
Omitted

F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:		
1. Device trade or proprietary name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Device common or usual name or classification name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Establishment registration number (only applies if establishment is registered)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Class into which the device is classified under (21 CFR Parts 862 to 892)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Action taken to comply with Section 514 of the Act	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	<input checked="" type="checkbox"/>	<input type="checkbox"/>



Yes
Present
Omission Justified

No
Inadequate
Omitted

<p>8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><i>pg 18</i></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>9. For class III devices only, a class III certification and a class III summary</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><i>N/A</i></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>10. Photographs of the device</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>11. Engineering drawings for the device with dimensions and tolerances</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>12. The marketed device(s) to which equivalence is claimed including labeling and description of the device</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>13. Statement of similarities and/or differences with marketed device(s)</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>14. Data to show consequences and effects of a modified device(s)</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>II. Additional Information that <u>is</u> necessary under 21 CFR 807.87(h):</p>		
<p>A. Submitter's name and address</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p>

Yes Present Omission Justified No Inadequate Omitted

B. Contact person, telephone number and fax number	<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant if applicable	N/A <input type="checkbox"/>	<input type="checkbox"/>
D. Table of Contents with pagination	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
III. Additional Information that <u>may be</u> necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Action taken to comply with voluntary standards	<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Performance data		
marketed device		
bench testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
animal testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
clinical data	<input type="checkbox"/>	<input type="checkbox"/>

Yes
Present
Omission Justified

No
Inadequate
Omitted

new device		
bench testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
animal testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
clinical data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E. Software information <i>N/A</i>	<input type="checkbox"/>	<input type="checkbox"/>
F. Hardware information <i>N/A</i>	<input type="checkbox"/>	<input type="checkbox"/>
G. If this 510(k) is for a kit, has the kit certification statement been provided? <i>N/A</i>	<input type="checkbox"/>	<input type="checkbox"/>
H. Is this device subject to issues that have been addressed in specific guidance document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, continue review with checklist from any appropriate guidance documents.		
If no, is 510(k) sufficiently complete to allow substantive review?		

Yes Present Omission Justified
No Inadequate Omitted

I. Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>
--------------------	--------------------------	--------------------------

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

February 02, 1994

CORDIS ENDOVASCULAR SYSTEMS, INC.
14740 N.W. 60TH AVENUE
MIAMI LAKES, FL 33014
ATTN: MARLENE WRIGHT

510(k) Number: K940187
Received: 13-JAN-94
Product: ENVOY GUIDING
CATHETER

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 USA
 Because of staff limitations, we cannot answer telephone 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.

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

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: _____
- 2. 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.

(Rev:2)

Requester signature



00-00001

K940187



510 (k) Premarket Notification Addendum

January 12, 1994

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center (HFZ-401), Room 452
1390 Piccard Drive
Rockville, Maryland 20850

Cordis Endovascular Systems, Inc.
14740 N.W. 60th Avenue
Miami Lakes, FL 33014 USA
(305) 824-8600
(305) 824-8610 Fax

100 CDRH/OCE/DID
12 10

REFERENCE: Cordis 6F 0.062" I.D. PTCA Guiding Catheter Modification - the Envoy™ Guiding Catheter

Dear Document Control Staff,

In accordance with section 510 (k) of the Food, Drug and Cosmetic Act, and in compliance with 21 CFR 807.81, Cordis Endovascular Systems, Inc., a subsidiary of Cordis Corporation, is submitting this premarket notification addendum for the Cordis 6F 0.062" I.D. Guiding Catheter (K915374, concurrence on 2-14-92). The purpose of this 510 (k) submission is to expand the guiding catheter line to include shapes which will be used in the peripheral and neurovasculature system. The Cordis Guiding Catheters have been reviewed by the Interventional Cardiology Branch within the Division of Cardiovascular, Respiratory and Neurological Devices.

Required information as discussed during a meeting with the Neurology Branch on October 26, 1993, immediately follows the Premarket Notification 510 (k) Checklist, with support documentation as attachments. An edited copy of the meeting memorandum can be found in Attachment IX.

Cordis Endovascular Systems considers our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market the device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331 (q).

Thank you in advance for your kind consideration of our application. If there are any questions, please feel free to contact me directly at (305) 824-8618 or Barbara Ramseyer, Vice President RA/QA for Cordis Corporation at (305) 824-2322.

Sincerely,

Marlene Wright
Marlene Wright, RAC
Manager, Regulatory Affairs and Clinical Research
Cordis Endovascular Systems, Inc.



PREMARKET NOTIFICATION 510 (K)

ENVOY Guiding Catheter

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Premarket Notification 510 (k) Checklist

K _____ Date DMC Received _____

Device Trade Name:

Reason for 510 (k):

Division/Branch:

Administrative Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

	Yes Present Omission Justified	No Inadequate Omitted
--	---	--------------------------------------

I. Critical Elements:

- | | | |
|---|-------|-------|
| A. Is the product a device? | [X] | [] |
| B. Is the device exempt from 510 (k) by regulation or policy? | [] | [X] |
| C. Is device subject to review by CDRH? | [X] | [] |
| D. (i) Are you aware that this device has been the subject of a previous NSE decision?
(ii) If yes, does this new 510 (k) address the NSE issue(s) (e.g., performance data)? | [] | [] |
| E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer

(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991) | [] | [] |
| F. Does the submission contain the information required under Sections 510 (k), 513(f), and 513 (i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?: | [X] | [] |

00-000004

- * Device trade or proprietary name [X]Page# 7 []
- * Device common or usual name or classification name [X]Page# 7 []
- * Establishment registration number (only applies if establishment is registered) [X]Page# 7 []
- * Class into which the device is classified under (21 CFR Parts 862 to 892) [X] Class II []
- * Classification Panel [X]Page# 7 []
- * Action taken to comply with Section 514 of the Act [X]Page# 7 []
- * Proposed labels, labeling and advertisements (if available) that describes the device, its intended use, and directions for use (Blue Book Memo #G91-1) [X]Page# 7 []
- * A 510 (k) summary of safety and effectiveness or a 510 (k) statement that safety and effectiveness information will be made available to any person upon request [X]Page# 18 []
- * For class III devices only, a class III certification and a class III summary Not Applicable - Not a Class III Device
- * Photographs of the device [] [X]
- * Engineering drawings for the device with dimensions and tolerances [X]Attach II []
- * The marketed device(s) to which equivalence is claimed including labeling and description of the device [X]Attach IV []
- * Statement of similarities and/or differences with marketed device(s) [X]Page# 16-17 []
- * Data to show consequences and effects of a modification [X]Page# 11-15

II. Additional Information that is necessary under 21 CFR 807.87(h):

- A. Submitter's name and address [X]Page# 1 []

number

- C. Representative/Consultant if applicable Not Applicable
- D. Table of Contents with pagination [X]Page# 2 []
- E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s) [X]Page# 7 (mfg) []
[X]Page # 10 (Steril)

III. Additional Information that may be necessary under 21 CFR 807.87(h):

- A. Comparison table of the new device to the marketed device(s) [X]Attach. III []

- B. Action taken to comply with voluntary standards Not Applicable

- C. Performance data

marketed device

- bench testing [X]Page# 11-14 []
- animal testing [X]Page# 14-15 []
- clinical data [] []

new device

- bench testing [X]Page# 11-14 []
- animal testing [X]Page# 14-15 []
- clinical data [] []

- D. Sterilization information [X]Page# 10 []

- E. Software information Not Applicable

- F. Hardware information Not Applicable

- G. Is this device subject to issues that have been addressed in specific guidance document(s)? [] [X]

If yes, continue review with checklist from any appropriate guidance documents [] []

If no, is 510 (k) sufficiently complete to allow substantive review? [X] []

- H. Other (specify) [] []

00-00006

IV. Additional Elements

- A. Biocompatibility information/data for patient contacting materials [X]Page# 15 []
- Certification of identical material/formulation [X]Attach. VI []
- B. List of all patient contacting materials in new device and compared to predicate device(s) [X]Page# 15 []



00-00007

DEVICE NAME:

Common Name - Guiding Catheter
Trade Name - ENVOY™ Guiding Catheter
Classification Name - Percutaneous Catheter

ESTABLISHMENT REGISTRATION NUMBER & ADDRESS:

#1016427
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes, FL 33014

MANUFACTURING SITE ADDRESS:

Cordis Endovascular Systems, Inc.
14740 NW 60th Avenue
Miami Lakes, FL 33014

CLASSIFICATION:

Guiding Catheters have been classified as Percutaneous Catheters, Class II, 21 CFR 870.1250 (74DQY). Division of Cardiovascular, Respiratory, & Neurological Devices.

PERFORMANCE STANDARDS

There are no performance standards applicable under Section 514 of the Food Drug and Cosmetic Act for Guiding Catheters.

DRAFT LABELING

Draft Labels and Instructions for Use can be found in Attachment I - Draft Labeling. The product literature/advertisements have not yet been developed.

BACKGROUND INFORMATION

The Cordis 6F PTCA Guiding Catheters (K915374) are used to guide and provide backup support for PTCA dilatation catheters during PTCA procedures. Cordis Endovascular Systems, Inc. which is a subsidiary of Cordis Corporation, intends to expand the 6F PTCA Guiding Catheter line to include additional shapes which will be used in the peripheral and neurovascular system. The trade name for the additional shapes will be the ENVOY Guiding Catheters.

The ENVOY Guiding Catheters are identical to the Cordis 6F PTCA Guiding Catheters except for the following:

(b)(4)

The ENVOY Guiding Catheters are used to guide and provide backup support (e.g. pushability) during intravascular procedures in the peripheral and neurovascular system. The guiding catheters are advanced into the arterial system over a guidewire and through a catheter sheath introducer or percutaneously. Once the desired site is achieved, the guidewire is removed and the guiding catheter acts as a guide and support mechanism for interventional/diagnostic devices. The devices (e.g. diagnostic catheters) are advanced coaxially through the guiding catheter and extend beyond the guiding catheter tip.

DEVICE DESCRIPTION - Refer to Attachment II - Product Drawing

Intended Use

The ENVOY Guiding Catheters are designed for the intravascular introduction of interventional/diagnostic devices in the peripheral and neurovascular system.

Description

The ENVOY Guiding Catheters are a single lumen catheter which features a (b)(4) body reinforced with tightly wound (b)(4). (b)(4) (b)(4) (b)(4) (b)(4)

(b)(4)

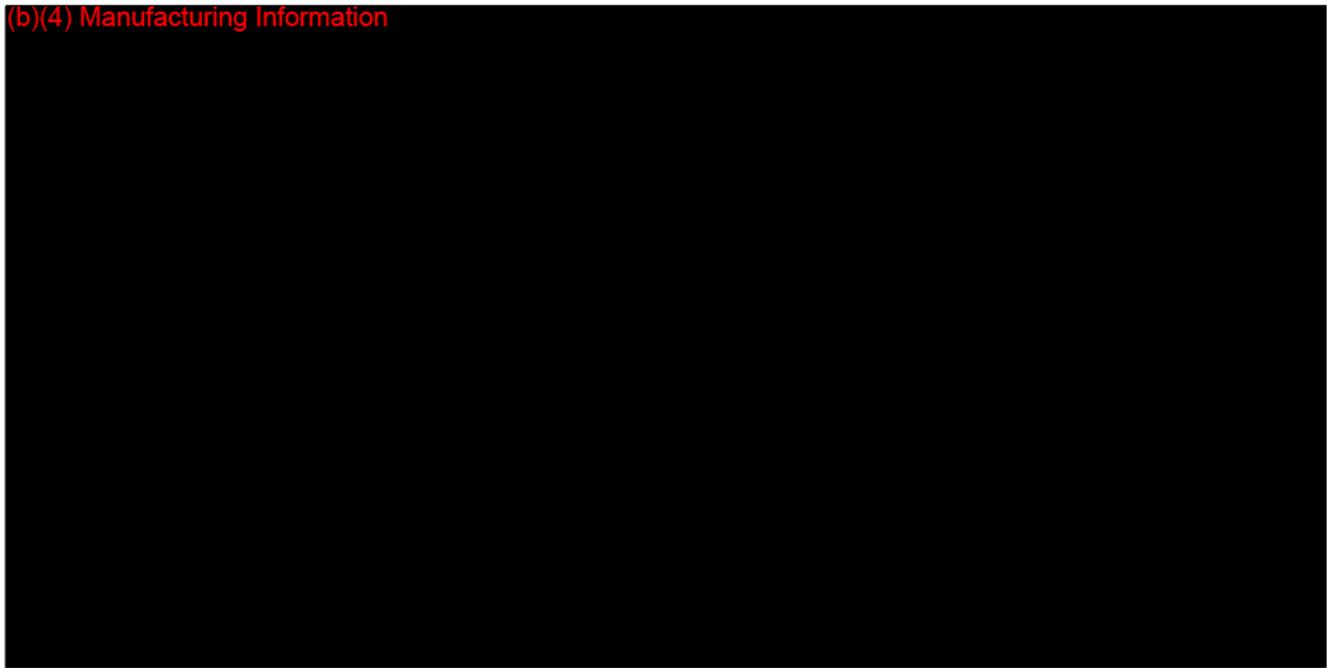
A. (b)(4) (b)(4) Shaft & (b)(4) - Refer to Attachment II

(b)(4)

(b)(4) Manufacturing Information



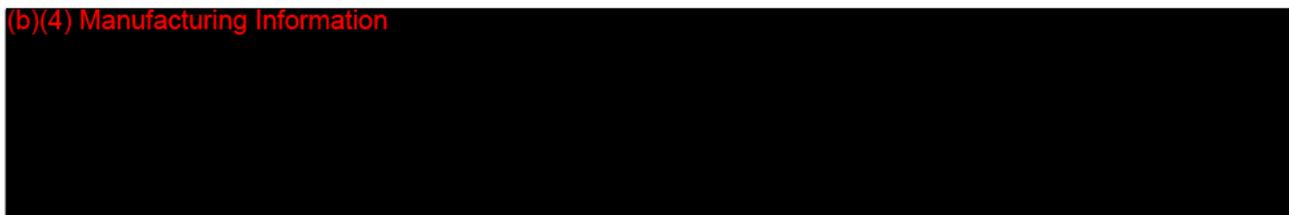
(b)(4) Manufacturing Information



The guiding catheters will be offered in lengths of 90 and 100 cm with an inside diameter of 0.062".

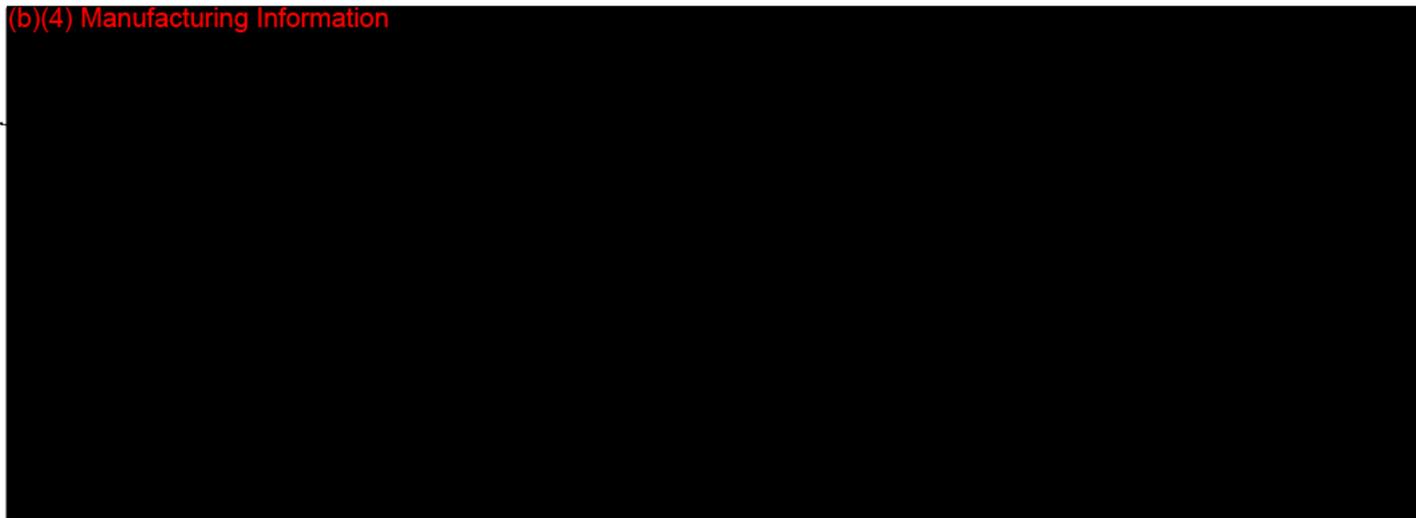
B. Braid Area - Refer to Attachment II

(b)(4) Manufacturing Information



00-00010

(b)(4) Manufacturing Information



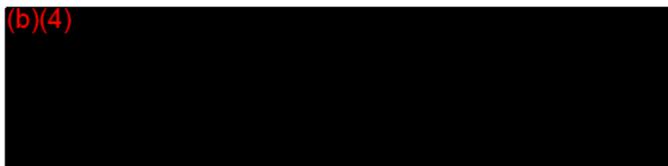
Manufacturing Process

The ENVOY Guiding Catheters are manufactured according to Good Manufacturing Practices. The process is similar to that used in manufacturing the Cordis 6F PTCA Guiding Catheters.

STERILIZATION, VALIDATION & RESIDUALS

The sterilization will be conducted by (b)(4) at the following address:

(b)(4)

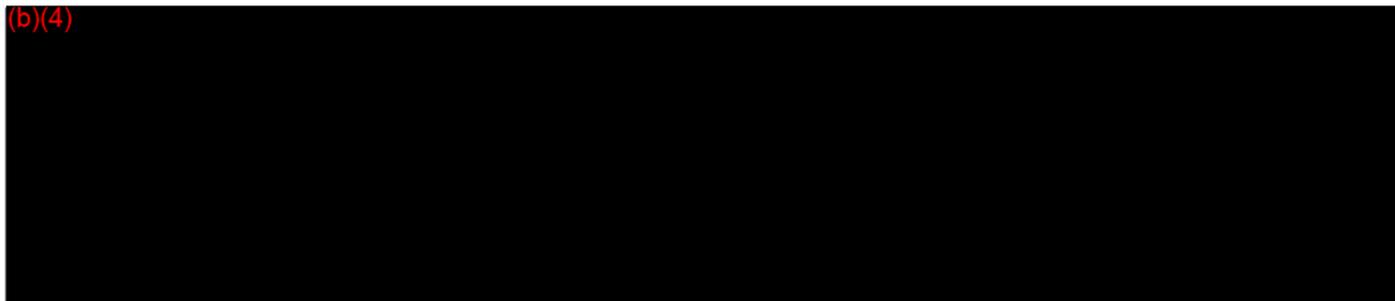


The sterilization process for the ENVOY Guiding Catheter is identical to that used for the Cordis 6F PTCA Guiding Catheters.

Sterilization of the product is achieved using (b)(4). The sterilization cycle used to sterilize the device is validated by using the (b)(4)

(b)(4)

(b)(4)



The catheters are pyrogen free. The (b)(4) testing method utilized at Cordis (b)(4) is according to the Guidelines on Validation of (b)(4) Test Center for Drug Evaluation and Research, Food and Drug Administration, December 1987. This is the same method used for the Cordis 6F PTCA Guiding Catheters.

PACKAGING

The ENVOY Guiding Catheters are packaged in an identical manner to that described and used for the Cordis 6F PTCA Guiding Catheter. The catheters are packaged in a (b)(4). The pouch is heat sealed using a validated process. The pouch is subject to random functional testing, followed by (b)(4). The catheters are packaged one per box and are labeled accordingly.

SHELF - LIFE TESTING

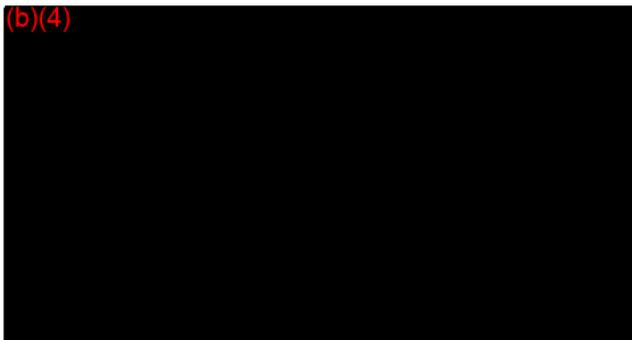
Cordis Endovascular Systems will use the same expiration date (3 years) for the ENVOY Guiding Catheters as the Cordis 6F PTCA Guiding Catheters since all materials are the same, along with, the same packaging, manufacturing process and sterilization.

PERFORMANCE DATA - Refer to Attachment V - Performance Data Test Results

(b)(4) Testing

The catheters were tested in-vitro to ensure the modifications being made to the Cordis 6F PTCA Guiding Catheters do not affect the safety or efficacy of the device. In addition, (b)(4) test and (b)(4) test was conducted to support the neurovascular indication. All testing was completed with sterilized ENVOY Guiding Catheters. The tests which were conducted are:

(b)(4)



(b)(4) Testing

BIOCOMPATIBILITY TESTING - Refer to Attachment VI - Material Certification

The Cordis Endovascular Systems ENVOY Guiding Catheter is indicated to be used as a guide and provide backup support in the peripheral and neurovasculature system.

All the materials used in the ENVOY Guiding Catheters are identical to the materials used in the Cordis 6F PTCA Guiding Catheters. The materials were shown to be biocompatible in support of 510 (k) K915374. **Refer to Attachment VI - Material Certification.**

Patient Contacting Materials

The materials which will come into contact with the patient are as follows:

(b)(4) Testing

Biocompatibility testing was conducted on the materials to support the Cordis 6F PTCA Guiding Catheter 510 (k) K915374. All materials were biocompatible.

Non-Contacting Patient Materials

The materials are as follows:

(b)(4) Testing

Biocompatibility testing was conducted on all materials to support the Cordis 6F PTCA Guiding Catheters 510 (k) K915374. All materials were biocompatible.

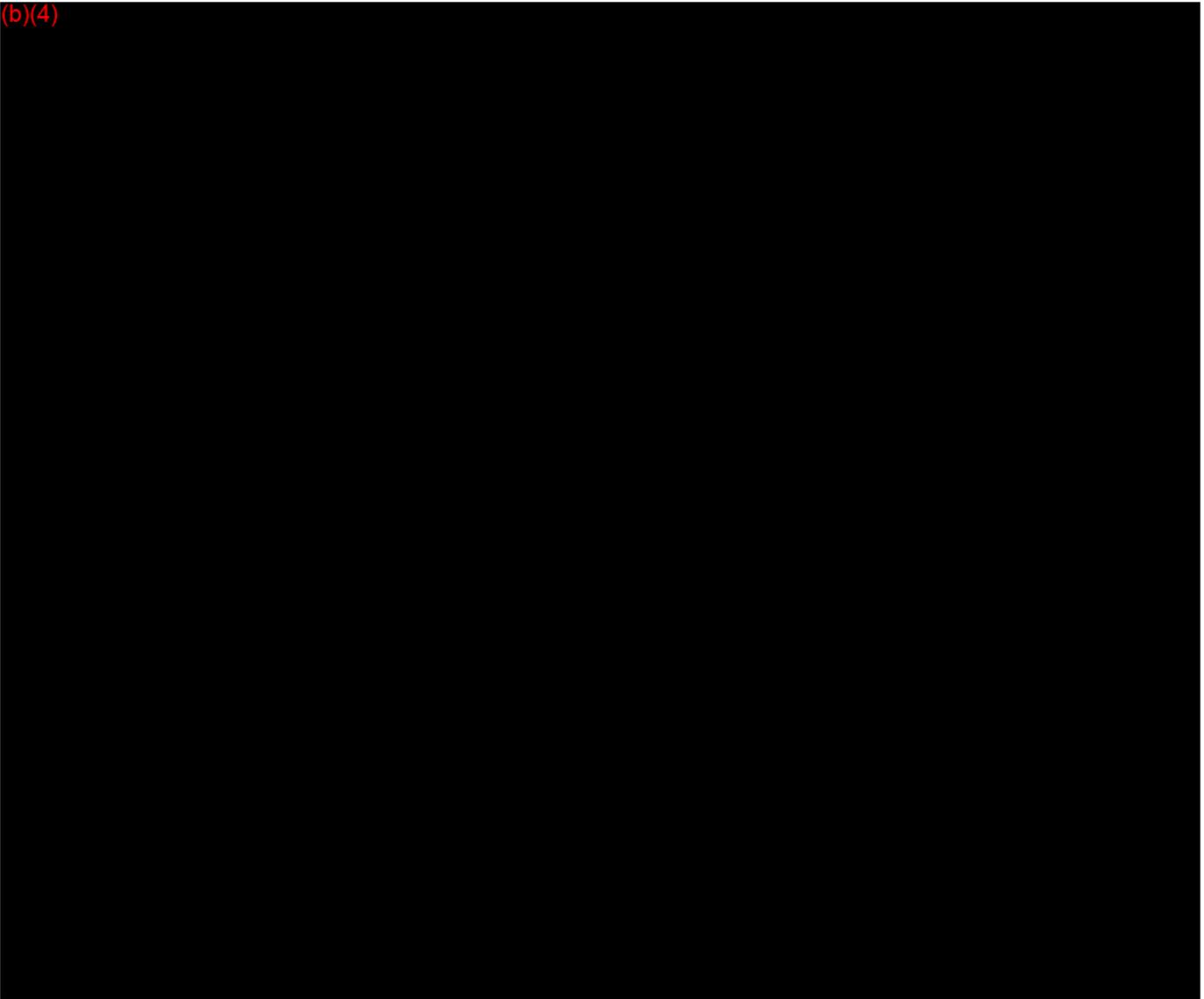
SUBSTANTIAL EQUIVALENCE - Refer to Attachment III - Substantial Equivalence Comparison Chart, Attachment IV - Predicate Device Labeling and Attachment VII - Predicate Device 510 (k)'s

The Cordis Endovascular Systems ENVOY Guiding Catheters are substantially equivalent to the following devices:

1. Cordis Corporation PTCA 6F Guiding Catheter (K915374) for design, manufacturing process, sterilization, packaging and indication.
2. Cordis 5.0 French Super Torque Catheters (K915836, concurrence on 2-11-92) for intended use.

The design differences are:

(b)(4)



(b)(4)

The similarities are:

1. Similar intended use as the Cordis 5.0 French Super Torque Catheters.
2. Same materials as the Cordis 6F PTCA Guiding Catheters. All materials have been shown to be biocompatible.
3. Same manufacturing process as the Cordis 6F PTCA Guiding Catheters.
4. Same packaging material, sealing technique and sterilization method as the Cordis 6F PTCA Guiding Catheters.
5. Same outside and inside diameters as the Cordis 6F PTCA Guiding Catheters.
4. Similar functionality results.

(b)(4) Testing

(b)(4) Testing

In summary, the ENVOY Guiding Catheter is substantially equivalent to the predicate devices.

510 (k) SUMMARY STATEMENT- Refer to Attachment VIII - 510 (k) Summary

A summary of safety and effectiveness for the Cordis ENVOY Guiding Catheter is provided as an attachment.

2/0

1

41



Envoy™ Guiding Catheter

Cordis Endovascular Systems, Inc.
14740 N.W. 60th Avenue
Miami Lakes, FL 33014 USA
(305) 824-8600
(305) 824-8610 Fax

Total Length: XXX cm

Usable Length: XXX cm

Tip Shape:

Outside Diameter: 6 French

Inside Diameter: 0.062 inch

Catalog Number: XXXXXXXXXXXX Lot Number: XXXXX

Sterilization Date: XX-XX Expiration Date: XX-XX

Contents: One ENVOY Guiding Catheter

Read Instructions for Use Prior to Use

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

Sterile. Non-Pyrogenic in unopened, undamaged package. Intended for single use only. Store in a cool, dry, dark place.

DRAFT

CES Logo Here

FDA SUBMISSION

DRAFT

Instructions for Use
Guiding Catheter

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. For one use only. Do not autoclave.

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

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

THERE IS NO EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON CORDIS ENDOVASCULAR SYSTEMS INC. (CES) PRODUCT(S) DESCRIBED IN THIS PUBLICATION. UNDER NO CIRCUMSTANCES SHALL CES BE LIABLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW. NO PERSON HAS THE AUTHORITY TO BIND CES TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

Descriptions or specifications in CES printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.



00-00021

Description

The Cordis Endovascular Systems (CES) Guiding Catheter has a large nontapered lumen that facilitates the peripheral and neurovascular passage of interventional devices.

Indications

The guiding catheter is designed for the intravascular introduction of interventional devices into the peripheral and neurovascular system.

Contraindications

None known.

Warnings

Discard the guiding catheter after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Accordingly, CES Inc. will not be responsible for any direct or consequential damages or expenses resulting from reuse of the catheter.

Do not use with Ethiodol or Lipiodol contrast media, or other such contrast media which incorporates the components of these agents.

Precautions

- Store in a cool, dark, dry place.
- Do not use open or damaged packages.
- Use prior to the "Use Before" date.
- Do not autoclave. Exposure to temperatures above 54oC (130oF) may damage the catheter.
- Do not expose to organic solvents.
- Inspect the guiding catheter before use to verify that its size, shape, and condition are suitable for the specific procedure.

- If strong resistance is met during manipulation, discontinue the procedure and determine the cause for the resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the catheter.
- Extreme care must be taken to avoid damage to the vasculature through which the catheter passes. The guiding catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to the following:

- air embolism
- hematoma at the puncture site
- infection
- perforation of the vessel wall.

Recommended Procedure

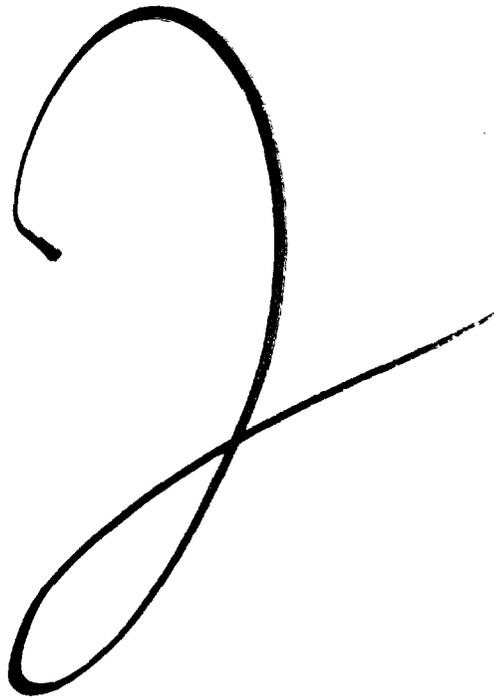
Introduce the guiding catheter over an appropriately sized guidewire using the vessel entry technique of choice. Administer local anesthesia prior to introduction.

The guiding catheter is preshaped to facilitate positioning.

1/5/94/bn
last rev. 1/10/94/ lhu



ATTACH II

A large, thick, black handwritten scribble or signature, possibly representing the number '2' or a stylized initial, located in the center of the page.A small, thin, black handwritten scribble or signature, possibly representing the number '44', located in the bottom right corner of the page.

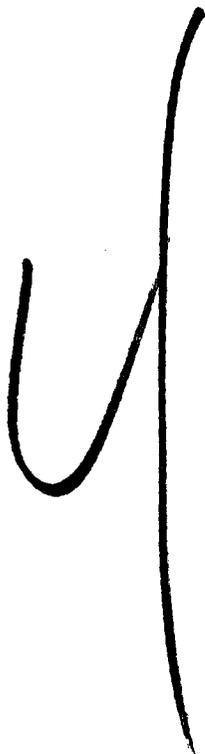
A large, handwritten mark in black ink, resembling a stylized number '3' or a cursive signature, centered on the page.

**ENVOY Guiding Catheter
Substantial Equivalence Comparison Chart
Intended Use and Materials**

Feature	Cordis 5.0 French Super Torque Catheters	Cordis 6F PTCA Guiding Catheter	CES ENVOY Guiding Catheter
Intended Use	Intravascular use for delivery of therapeutic and diagnostic agents/devices	Introduction of interventional devices in the peripheral and coronary vasculature	Introduction of interventional devices in the peripheral and neurovasculature
Hub Material	(b)(4)		
Strain Relief Material			
Shaft Material			
Inner Lining			
Outer Coating			
Shaft Braid			

09-00029



A large, handwritten mark or signature in black ink, consisting of a vertical line with a loop on the left side.A small, handwritten mark or signature in black ink, consisting of a few loops and a vertical line.

PTCA

562-623

GUIDING CATHETER

JL 4

6 F .062" I.D.

100 cm

**JUDKINS TECHNIQUE
LEFT CORONARY**

4 CM. STANDARD CURVE

/0001

00-00032

562-623 **PTCA**
JL 4

PTCA
562-623
GUIDING CATHETER

JL 4

6 F .062" LD.
100 cm

JUDKINS TECHNIQUE
LEFT CORONARY
4 CM. **STANDARD** CURVE

/ 00001



00-00033
151-0577.1

Instructions for Use Guiding Catheter

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. For one use only. Do not autoclave.

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

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

THERE IS NO EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE IN THE CORDIS PRODUCTS DESCRIBED IN THIS INSTRUMENT. THE USER SHALL ACCEPT THE RISK OF THE CORDIS PRODUCTS AS DESCRIBED ON ANY INSTRUMENT, LABEL, OR PACKAGE. CORDIS CORPORATION SHALL NOT BE RESPONSIBLE FOR ANY DAMAGE TO ANY EQUIPMENT, TO ANY OF THE PRESENTATION OR TO ANY OF THE SPECIFICALLY IDENTIFIED LITIGATION.

Description of some conditions of Cordis products and their use, including, but not limited to, the use of the product, are set forth to assist in the use of the product. The product is not intended to be used in any manner not expressly warranted.

Description

The Cordis Guiding Catheter has a large nonoperated lumen that facilitates the intravascular passage of interventional devices.

Indications

The guiding catheter is designed for the intravascular introduction of interventional devices.

Contraindications

None known

Warnings

Discard the guiding catheter after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Accordingly, Cordis Corporation will not be responsible for any direct or consequential damages or expenses resulting from reuse of the catheter.

Do not use with Erihidol or Lipiodol contrast media, or other such contrast media which incorporates the components of these agents.

Precautions

- Store in a cool, dark, dry place.
- Do not use open or damaged packages.
- Use prior to the "Use Before" date.
- Do not autoclave. Exposure to temperatures above 54°C (130°F) may damage the catheter.
- Do not expose to organic solvents.
- Inspect the guiding catheter before use to verify that its size, shape, and condition are suitable for the specific procedure.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause for the resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the catheter.
- Extreme care must be taken to avoid damage to the vasculature through which the catheter passes. The guiding catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to the following:

- air embolism
- hematoma at the puncture site
- infection
- perforation of the vessel wall.

Recommended Procedure

Introduce the guiding catheter over an appropriately sized guidewire using a percutaneous entry technique of choice. Administer local anesthesia during introduction.

The guiding catheter is preshaped to facilitate positioning.



GUIDING CATHETERS

1. Diagnostic angiographic catheters with neuro-shapes.
 - * Meditech K864118 - 5F Catheters
 - * Cordis K915836 - 5F Catheters
 - * Cook K914856 - 5F, 6F and 7F Catheters
 - * AngioDynamics K914199 - 4F, 5F, and 6F Catheters
 - * USCI Bard - 7F Catheters
2. Same outside diameter as corresponding diagnostic catheter.
3. Larger inside diameter as corresponding diagnostic catheter.



DIAGNOSTIC CATHETERS WITH NEURO SHAPES

- * Medi*tech Glidecath™ Hydrophilic-Coated Catheters
5F Catheters K864118
product literature

- * Cordis Diagnostic Catheters
5.0F Catheters K915836
510 (k) concurrence letter
List of products in the 510 (k) submission

- * Cook Incorporated Angiographic Catheters
5F, 6F and 7F Catheters K914856
product literature

- * AngioDynamics Soft-tip Catheters
4F, 5F and 6F Catheters K914199
product literature
List of products in the 510 (k) submission



Glidecath[®]-00036

Hydrophilic-Coated Catheters



Overcoming Friction for Smooth Distal Access

 **Medi·tech**[®]
Boston Scientific Corporation

42

Glidecath™ 00-00037

Hydrophilic-Coated Catheters

Hydrophilic coating and advanced catheter construction provide superior performance for...

- *injection of contrast media*
- *administration of drugs*
- *delivery of therapeutic materials*

Glidecath features advanced hydrophilic coating.

- Dramatically reduces catheter surface friction for smooth negotiation of tortuous and distal anatomy
- Reduced friction between the catheter and vessel wall minimizes trauma

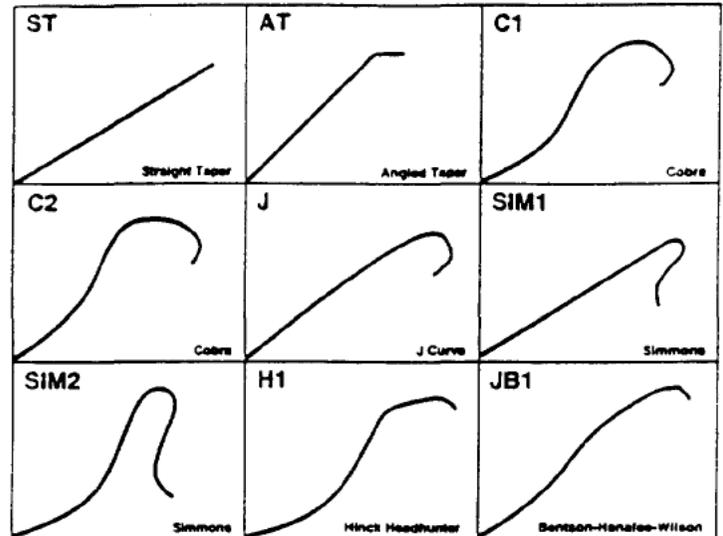
Glidecath tracks with ease over guidewires.

- Flexible catheter material has excellent tracking characteristics
- Trackability is further enhanced when combined with the Glidewire™ for a totally hydrophilic system

Glidecath has superior torque control.

- 5Fr braided design allows precise torque control
- Extremely low friction between catheter and vessel wall improves torque response
- Uncoated proximal end facilitates catheter manipulation

Shape Selector



Ordering Information

Order Number	Size (Fr)	Length (cm)	Tip Shape	End Hole (in)	Flow Rate* (cc/sec)
32-130	5	65	ST	.038	22
32-133	5	100	ST	.038	19
32-136	5	65	AT	.038	22
32-139	5	100	AT	.038	19
32-142	5	65	C1	.038	22
32-145	5	65	C2	.038	22
32-148	5	65	J	.038	22
32-151	5	100	SIM1	.038	19
32-154	5	100	SIM2	.038	19
32-157	5	100	H1	.038	19
32-160	5	100	JB1	.038	19

*All measurements taken at 1000 psi and 37° C using Renografin® 76.

Packaged five per box

Glidecath and Glidewire are trademarks of Terumo Corporation
Renografin is a registered trademark of Squibb & Co.

#215⁰⁰ per box
5 per box

 **Medi-tech®**
Boston Scientific Corporation

480 Pleasant Street Watertown, MA 02172

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

Ordering Information (800) 225-3238

DT990 3-91 7.5M

1992 Boston Scientific Corporation Printed in U.S.A.

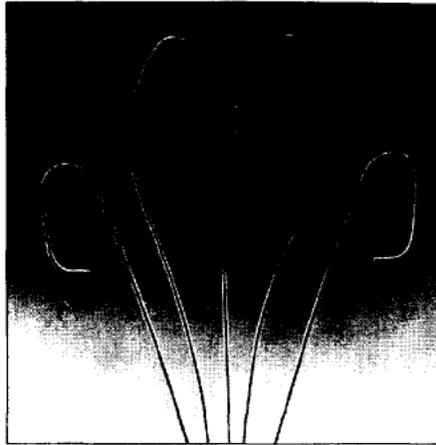
Cordis Corporation

More than Thirty Years
of Biomedical Innovation,
Market Leadership, and
Customer Care

Cordis was founded in 1959 by William P. Murphy, Jr., M.D. in Miami, Florida. Started in Dr. Murphy's garage, the Company now operates modern production facilities in both the United States and Europe, employing more than 2100 people. Today's Company produces and markets sophisticated medical products throughout the world, and as always, remains committed to its corporate mission of developing and applying innovative technologies to assist physicians in sustaining and improving human life.

Cordis' basic orientation has been clear from the start. The name "Cordis" is Latin for "of the heart," a fact that reflects — both in 1959 and now — its primary interest in the human cardiovascular system.

Throughout much of its corporate existence, Cordis was perhaps best known for cardiac pacemakers, a business the Company helped to



A sampling of Cordis diagnostic catheters.

pioneer during the early 1960s and, as part of a strategic realignment, completely divested in 1987. Today, the Company stands as a recognized leader in angiography and radiology. Cordis' association with angiography goes back some 30 years. The Company has been in the forefront of this medical specialty — which involves the diagnosis and management of problems associated with the vascular system — since the late 1950s when it introduced the Intercalative Angiograph, one of its first commercial products and the industry's first synchronized, high-pressure injector. Since then, Cordis has pioneered numerous other breakthroughs in this specialty and has established a reputation as a premier supplier of high-quality angiographic devices.

From their inception, Cordis Ducor catheters revolutionized the industry. Introduced in 1966, these catheters provide several advantages that remain the standard for the industry. The major characteristics offered by Ducor catheters, and the construction features that make them possible, include:

Positional Stability made possible by the use of preformed curves that match or complement the anatomy of the vessel.

Minimal damage to vessels resulting from the use of a soft, atraumatic flexible polyurethane that has excellent memory and retains its preformed configuration.

Excellent torque control and maneuverability made possible by a stainless steel wire braid (except in the tip) encapsulated between the smooth external and internal walls of standard Ducor catheters. The braid provides an excellent torque ratio between the hub end and the catheter tip.

Since the 1960's, Cordis has continued to develop and market new catheter designs for diagnostic angiography. Working closely with physicians, pre-formed catheters were developed which made safe, rapid selective arteriography possible. Catheter designs such as the Sidewinder, Cobra and Headhunter were all developments jointly pioneered by Cordis. With the development of wire-braided catheter technology, Cordis brought to the physician a new level of torque response for selective catheterization.

Cordis catheters typically undergo approximately 40 different operations, plus 25 inspections and audits and are designed to provide superior performance characteristics. Each catheter is engineered to maximize features such as: high flow rates; superior shape retention; high radiopacity; enhanced torque-control; kink-resistance; soft, atraumatic tip; and convenient packaging.

Intended Use

Cordis diagnostic catheters enable the physician to perform angiography quickly and consistently with minimal risk to the patient. Flush and selective catheters for visualization of head and neck, visceral, coronary and peripheral vessels are available in a variety of sizes and configurations.

In addition, Cordis offers a complete line of accessory products for use with diagnostic catheters.

Product Line Introduction: Catheters

A variety of catheter types are available, depending on the application. *Flush catheters* are designed with a large lumen and high strength to deliver

contrast medium rapidly and effectively into the vasculature for regional opacification. *Selective catheters* are generally wire-braided to achieve greater torque for enhanced maneuverability to selectively opacify a particular vessel.

Flush Catheters

Super Flow flush catheters are available in 5.2 French size in various lengths. Made of polyurethane, the large lumen and soft, highly radiopaque tip design facilitates catheter placement and rapid contrast medium delivery. *Super Flow* flush catheters can withstand 800 psi injection pressure.

Super Torque flush catheters are available in 4.1 and 5.2 French sizes in various lengths. Made of a special blend of polyurethane, these wire-braided catheters have a relatively large lumen for rapid contrast media delivery with exceptional kink-resistance, and a soft tip feature found in selective catheters. Maximum injection pressure is 1200 psi.

Standard flush catheters are available in 6, 7 and 8 French sizes in various lengths. Made of polyurethane, these wire-braided catheters are exceptionally kink-resistant, and provide a high degree of torque and pushability. Maximum injection pressure is 1050 psi.

Selective Catheters

Super Flow selective catheters are available in 5.2 French sizes in a variety of lengths and shapes. Made of polyurethane, these catheters exhibit high torque without the incorporation of wire braiding, thus allowing for a relatively large lumen. Maximum injection pressure is 1000 psi.

Super Torque selective catheters are available in 4.1, 6 and 7 French sizes in a variety of lengths and shapes. Made of a special blend

of polyurethane, these wire-braided catheters exhibit a high degree of torque control with a large lumen for greater flow rate. Maximum injection pressure is 1200 psi.

Super Torque Plus selective catheters are similar to *Super Torque* catheters, but also incorporate an additional soft, distal tip segment.

Thin Wall selective catheters are available in 5 and 6 French sizes in several lengths and shapes. Made of polyurethane, these non-braided catheters have a thin-wall design to provide greater flow rates at lower pressure. Maximum injection pressure is 500 psi.

Catheter Identification

Cordis catheters are distinguished by color-coded printing by French size on the hub to insure easy recognition.

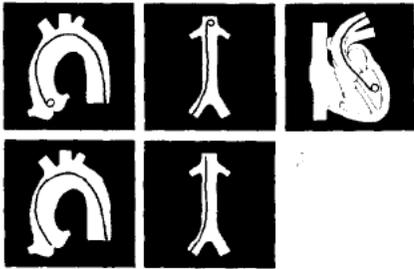
Each catheter type is identified by the first three digits of the catalog numbers indicated below:

Super Torque Plus	533-xxx
Super Torque	532-xxx
High Flow	527-xxx
Standard	521-xxx 523-xxx 524-xxx 525-xxx
Thin Wall	521-xxx
Super Flow	528-xxx

Catheter Shapes

00-00040

Flush Catheters^{1,2}



PIG



STR

Headhunter^{3,4}



H1



H3



H4



H1H



H3H

Sidewinder^{5,6}



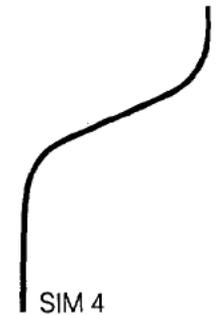
SIM 1



SIM 2



SIM 3



SIM 4

Newton⁷



HN 1



HN 2



HN 3



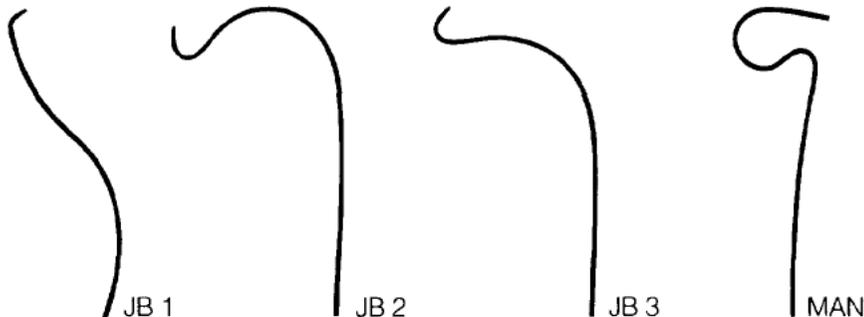
HN 4



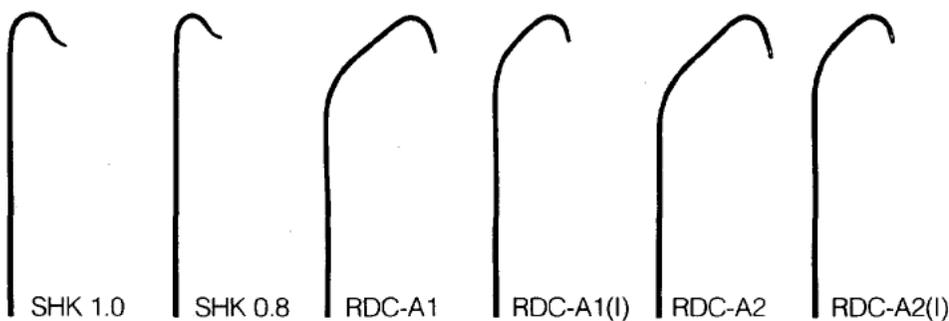
HN 5

44

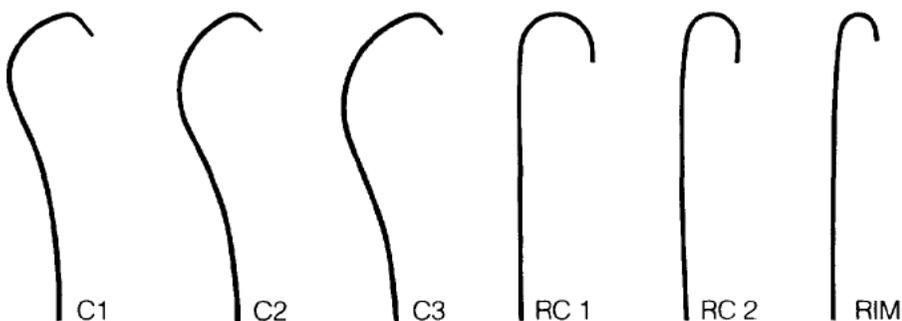
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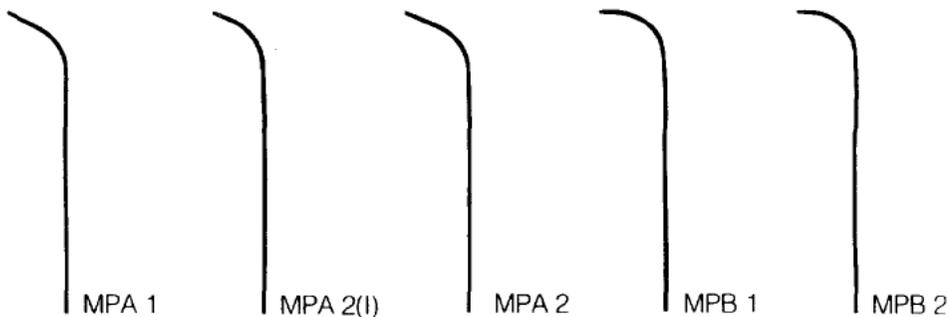
Bentson, Mani^{8,9}



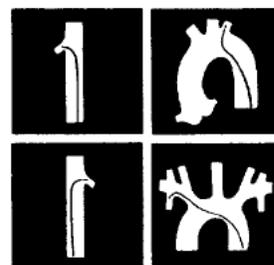
Sheperd Hook, Renals¹⁰



Cobra, J Curve^{11,12}



Multipurpose¹³



Handwritten signature and the number 9.

Cerebral Catheters Headhunter

Open end, no side holes.

Records processed under FOIA Request # 2015-8094; Released by CDRH on 12-10-2015
These catheters were designed for use with the technique described by VA Hinck, MD, for the selective catheterization (via the percutaneous femoral approach) of the arteries supplying the cerebral cortex, including the left and right internal carotids, and the left and right external carotids.

This product is packaged five (5) per box.

Price (per unit):
Each catalog number must be ordered in units of five (5).

Catalog Number	French Size	Catheter Type	Guidewire Dia., inches	Length, cm	Curve Style	Remarks	5-95 units	100+ units
532-461	4.1	Super Torque	.035	100	H1	Moderately tortuous arch	\$16.50	\$15.50
532-463	4.1	Super Torque	.035	100	H3	Undilated arch	16.50	15.50
528-560	5.2	Super Flow	.035	100	H1	Moderately tortuous arch	16.50	15.50
528-562	5.2	Super Flow	.035	100	H3	Undilated arch	16.50	15.50
523-660	6	Standard	.035	100	H1	Moderately tortuous arch	16.25	15.25
523-760	7	Standard	.038	100	H1	Moderately tortuous arch	16.25	15.25
523-762	7	Standard	.038	100	H3	Undilated arch	16.25	15.25
523-764	7	Standard	.038	100	H4	Dilated tortuous arch	16.25	15.25
523-860*	8	Standard	.038	100	H1	Moderately tortuous arch	16.25	15.25

Cerebral Catheters Headhunter (Hilal Modification)

Open end, no side holes.

These catheters are the same as Headhunter H1 and H3 except that the tips are more flexible as a result of the 3 cm taper.

This product is packaged five (5) per box.

Price (per unit):
Each catalog number must be ordered in units of five (5).

Catalog Number	French Size	Catheter Type	Guidewire Dia., inches	Length, cm	Curve Style	Remarks	5-95 units	100+ units
523-661	6	Standard	.035	100	H1H	Moderately tortuous arch	\$16.25	\$15.25
523-761	7	Standard	.038	100	H1H	Moderately tortuous arch	16.25	15.25
523-763	7	Standard	.038	100	H3H	Undilated arch	16.25	15.25

*To be discontinued.

Modifications to the above products are available by request. Please note that in most cases delivery will take 4-6 weeks. However, the time will vary depending upon the complexity of the request and the availability of required materials. If there are any questions concerning specific capabilities, delivery times, or pricing, please contact your Cardis Sales Representative.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8094; Released by CDRH on 02-02-2015

00-00043

**Cerebral Catheters
Sidewinder
(Simmons Technique)**

These catheters were designed for use in visualizing the tortuous vessels of the aortic arch. The catheters are especially useful for visualizing a left common carotid artery that is otherwise inaccessible because of origin or position.

Open end, no side holes.

This product is packaged five (5) per box.

Price (per unit):
Each catalog number must be ordered in units of five (5).

Catalog Number	French Size	Catheter Type	Guidewire Dia., inches	Length, cm	Curve Style	5-95 units	100+ units
532-414	4.1	Super Torque	.035	100	SIM 1	\$16.50	\$15.50
532-415	4.1	Super Torque	.035	100	SIM 2	16.50	15.50
532-416	4.1	Super Torque	.035	100	SIM 3	16.50	15.50
528-514	5.2	Super Flow	.035	100	SIM 1	16.50	15.50
528-515	5.2	Super Flow	.035	100	SIM 2	16.50	15.50
528-516	5.2	Super Flow	.035	100	SIM 3	16.50	15.50
523-614	6	Standard	.035	100	SIM 1	16.25	15.25
523-615	6	Standard	.035	100	SIM 2	16.25	15.25
523-616	6	Standard	.035	100	SIM 3	16.25	15.25
523-617	6	Standard	.035	100	SIM 4	16.25	15.25
523-714	7	Standard	.038	100	SIM 1	16.25	15.25
523-715	7	Standard	.038	100	SIM 2	16.25	15.25
523-716	7	Standard	.038	100	SIM 3	16.25	15.25
523-717	7	Standard	.038	100	SIM 4	16.25	15.25

Modifications to the above products are available by request. Please note that in most cases delivery will take 4-6 weeks. However, the time will vary, depending upon the complexity of the request and the availability of required materials. If there are any questions concerning specific capabilities, delivery times, or pricing, please contact your Cordis Sales Representative.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Cerebral Catheters (Newton Technique)

These catheters were designed for use with the techniques described by TH Newton, MD, for the selective catheterization of the cerebral arteries.

Open end, no side holes.

This product is packaged five (5) per box.

Price (per unit):
Each catalog number must be ordered in units of five (5).

Catalog Number	French Size	Catheter Type	Guidewire Dia., inches	Length, cm	Curve Style	5-95 units	100+ units
522-493	4.1	Super Torque	.035	100	HN 3	\$16.50	\$15.50
522-494	4.1	Super Torque	.035	100	HN 4	16.50	15.50
521-591	5	Thin Wall	.035	100	HN 1	13.25	12.25
521-592	5	Thin Wall	.035	100	HN 2	13.25	12.25
521-593	5	Thin Wall	.035	100	HN 3	13.25	12.25
521-594	5	Thin Wall	.035	100	HN 4	13.25	12.25
521-595	5	Thin Wall	.035	100	HN 5	13.25	12.25
528-571	5.2	Super Flow	.035	100	HN 4	16.50	15.50

Cerebral Catheters (Bentson Technique)

These catheters were designed for use with the techniques described by JR Bentson, MD, for selective catheterization of the cerebral arteries.

Open end, no side holes.

This product is packaged five (5) per box.

Price (per unit):
Each catalog number must be ordered in units of five (5).

Catalog Number	French Size	Catheter Type	Guidewire Dia., inches	Length, cm	Curve Style	5-95 units	100+ units
532-436	4.1	Super Torque	.035	100	JB 1	\$16.50	\$15.50
532-437	4.1	Super Torque	.035	100	JB 2	16.50	15.50
532-438	4.1	Super Torque	.035	100	JB 3	16.50	15.50
528-536	5.2	Super Flow	.035	100	JB 1	16.50	15.50
528-537	5.2	Super Flow	.035	100	JB 2	16.50	15.50
528-538	5.2	Super Flow	.035	100	JB 3	16.50	15.50

Modifications to the above products are available by request. Please note that in most cases delivery will take 4-6 weeks. However, the time will vary, depending on the complexity of the request and the availability of required materials. If there are any questions concerning specific capabilities or delivery times, please contact FDA/CDRH/OE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Diagnostic Radiology
00-00043

These catheters were designed for use with a technique described by RL Mani, MD, for the selective catheterization of the cerebral arteries.

**Cerebral Catheters
(Mani Technique)**

Open end, no side holes.

This product is packaged five (5) per box.

Price (per unit):
Each catalog number must be ordered in units of five (5).

Catalog Number	French Size	Catheter Type	Guidewire Dia., inches	Length, cm	Curve Style	5-95 units	100+ units
532-470	4.1	Super Torque	.035	100	MAN	\$16.50	\$15.50
528-570	5.2	Super Flow	.035	100	MAN	16.50	15.50

Modifications to the above products are available by request. Please note that in most cases delivery will take 4-6 weeks. However, the time will vary depending on the product. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA@FDA.HHS.gov or 301-796-8148. Use of specific capabilities, delivery times, or pricing please contact your Cordis Sales Representative.

TORCON NB[®] ADVANTAGE



SELECTIVE ANGIOGRAPHIC CATHETERS



COOK[®]

Cook Incorporated

Preformed Angiographic Catheters - Selective

Cerebral Curves - Positrol II Catheter

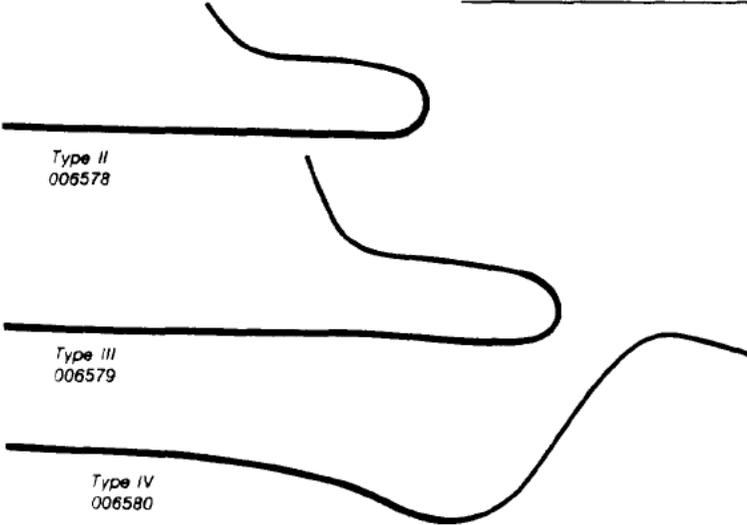
Catalog Number	Tip Curve Length	Size	Max. O.D. of Guide Wire Catheter Will Accept (in.)(mm)	Length (cm)	Price Each		
					10 Per Box	Comb. of 50	Comb. of 100
Headhunter Type Sterile. No side holes.							
006576	Type I	7F	.038(1.0)	100	\$17.25	\$16.50	\$15.75
006577	Type III	7F	.038(1.0)	100	17.25	16.50	15.75



Catalog Number	Tip Curve Length	Size	Max. O.D. of Guide Wire Catheter Will Accept (in.)(mm)	Length (cm)	Price Each		
					10 Per Box	Comb. of 50	Comb. of 100
Berenstein Catheter Sterile. 10cm taper to 5F. 105° tip curve.							
006581		7F	.038(1.0)	110	\$17.25	\$16.50	\$15.75



Catalog Number	Tip Curve Length	Size	Max. O.D. of Guide Wire Catheter Will Accept (in.)(mm)	Length (cm)	Price Each		
					10 Per Box	Comb. of 50	Comb. of 100
Simmons Type* (Side-winder) Sterile. No side holes.							
006578	Type II	7F	.038(1.0)	100	\$17.25	\$16.50	\$15.75
006579	Type III	7F	.038(1.0)	100	17.25	16.50	15.75
006580	Type IV	7F	.038(1.0)	100	17.25	16.50	15.75



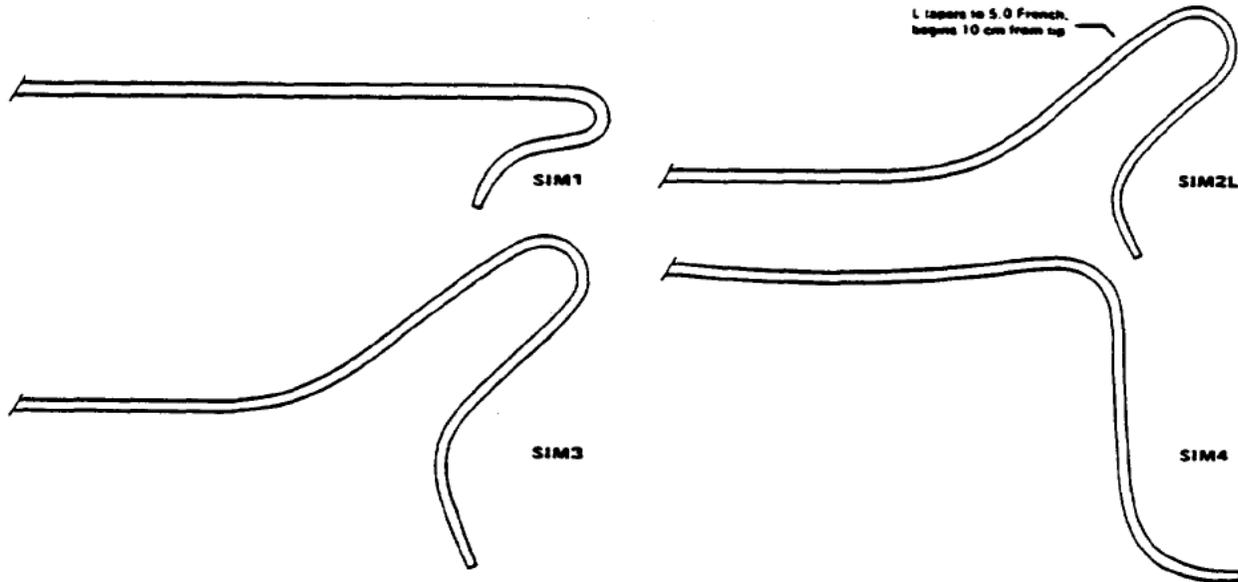
*Additional types available, See Visceral Curves.

3

CEREBRAL CATHETERS

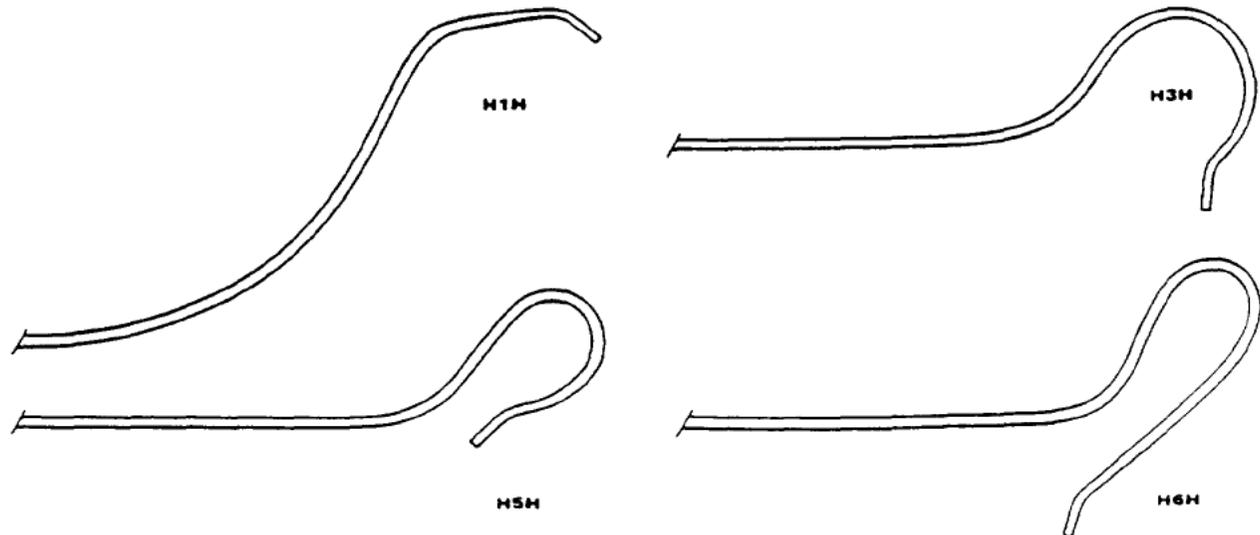
SIMMONS CEREBRAL CATHETERS

The SIM1 catheter tip configuration is used in a narrow aorta, the SIM2, in a moderately narrow aorta, the SIM3, in a wide aorta, and the SIM4, in an elongated aorta. A 3cm catheter tip taper to 5.0 French is indicated by adding an "H" to a tip configuration suffix. A 10cm catheter tip taper to 5.0 French is indicated by adding an "L" to a tip configuration suffix (Example: SIM2L).



HILAL MODIFIED HEADHUNTER CEREBRAL CATHETERS

The H1H, H3H, H5H, and H6H catheter tips have a 3cm taper to 5.0 French. The H1H is used in entering the branch artery directly, the H3H is used in entering the branch artery by hooking back from the opposite direction. The H5H is used for hooking back in the left carotid arising at a sharp angle from the aorta with a high arch. The H6H permits injection near or beyond the carotid bifurcation.



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CATHETER FLOW RATES

Flow rates shown are determined *in vitro* using the Cook Pressure Injector and 100% Renografin®-76 at room temperature (25° C). Increasing the temperature of the contrast medium (i.e., to 37° C) or using a less viscous contrast medium, will result in an increase in flow rate. Since a number of variables can produce different flow rates, the following information should be used only as a guide.

CATHETER		MAXIMUM FLOW RATE	MAXIMUM RECOMMENDED PRESSURE	
French Size	Length cm	cc/sec	kg/cm ²	psi
		100% Renografin®-76		
5.0	65	15	84	1200
5.0	100	11	84	1200
6.0	65	24	84	1200
6.0	100	18	84	1200
7.0	65	33	84	1200
7.0	100	28	84	1200

COOK INCORPORATED
 A COOK GROUP COMPANY
 P.O. Box 489
 Bloomington, IN 47402 U.S.A.
 Phone: 812 339-2235
 Toll Free: 800 457-4500

COOK (CANADA) INC.
 A COOK GROUP COMPANY
 111 Sandiford Drive
 Stouffville, Ontario L4A 7X5 CANADA
 Phone: 416 640-7110
 Toll Free: 800 668-0300

WILLIAM A. COOK AUSTRALIA PTY. LTD.
 A COOK GROUP COMPANY
 Brisbane Technology Park
 12 Electronics Street
 Eight Mile Plains
 Brisbane, QLD 4113 AUSTRALIA
 Phone: 07 841-1188

TO ORDER, FOLLOW THE ARROWS: (Example: HNB5.0-35-100-MC-NS-H1)

1	2	3	4	5	6	
ORDER NUMBER PREFIX	WIRE GUIDE DIAMETER inches millimeters	LENGTH cm	FITTING Metal Luer lock	SIDE-PORTS	TIP CONFIGURATION	Remarks
FRENCH SIZE	0.38 0.38 0.89 0.97					

CEREBRAL CATHETERS
HINCK HEADHUNTER

HNB5.0	35	100	MC	NS ¹	H1 H3	H1 for branch artery entered directly; H3 for branch artery entered by hooking back from opposite direction
HNB6.0	38	100	M	NS	H1 H3	
HNB7.0	38	100	M	NS	H1 H3	

SIMMONS

HNB5.0	35	100	MC	NS	SIM1 SIM2 SIM3	SIM1 for narrow aorta; SIM2 for moderately narrow aorta; SIM3 for wide aorta
HNB6.0	38	100	M	NS	SIM1 SIM2 SIM3	
HNB7.0	38	100	M	NS	SIM1 SIM2 SIM3	

BENTSON-HANAFEE-WILSON

HNB5.0	35	100	MC	NS	JB1 JB2 JB3	JB1 for most patients; JB2 for tortuous origin of branch arteries; JB3 for arteries with an acute angle of origin from the aorta
HNB6.0	38	100	M	NS	JB1 JB2 JB3	
HNB7.0	38	100	M	NS	JB1 JB2 JB3	

VISCERAL CATHETERS
COBRA

HNB5.0	35	65	MC	NS	C1 C2 C3	C1 for child; C2 for small adult; C3 for adult
HNB6.0	38	65	M	NS	C1 C2 C3	
HNB7.0	38	65	M	NS	C1 C2 C3	

SELECTIVE AND SUPERSELECTIVE

HNB5.0	35	65	MC	NS	RC1 RC2 RIM RH	RC1 for celiac and superior mesenteric arteries in large patients; RC2 for celiac and superior mesenteric arteries in small patients; RIM for inferior mesenteric artery; RH for hepatic artery
HNB6.0	38	65	M	NS	RC1 RC2 RIM RH	
HNB7.0	38	65	M	NS	RC1 RC2 RIM RH	

¹NS=No sideports

HNB8.0 French Selective Angiographic Catheters may be ordered in the appropriate diameter, length, fitting, sideports and tip configurations shown on this product information sheet. (Example: HNB8.0-38-100-M-NS-H1)

**TORCON NB® ADVANTAGE
SELECTIVE ANGIOGRAPHIC CATHETERS**

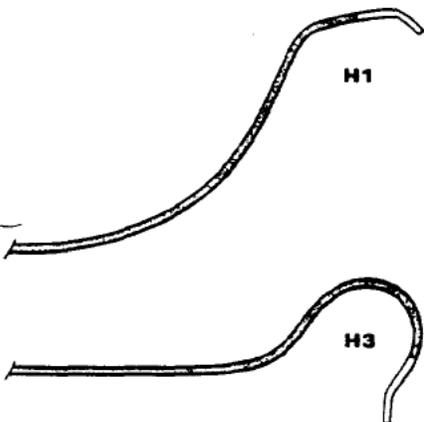
THE ADVANTAGE – A flexible, atraumatic distal catheter tip which maintains stability during injection.

THE ADVANTAGE – An uniquely constructed nylon catheter with stainless steel braiding which provides superior torque control to the catheter tip.

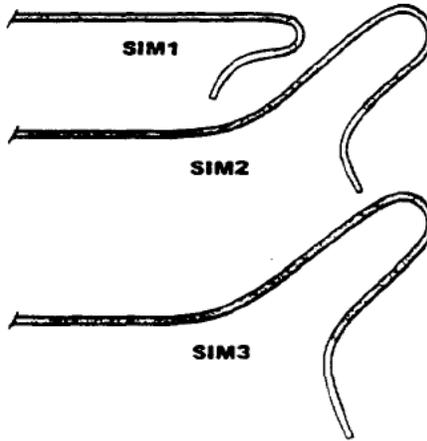
THE ADVANTAGE – A larger internal diameter in 6.0, 7.0 and 8.0 French, thereby allowing higher flow rates with less resistance.

CEREBRAL CATHETERS

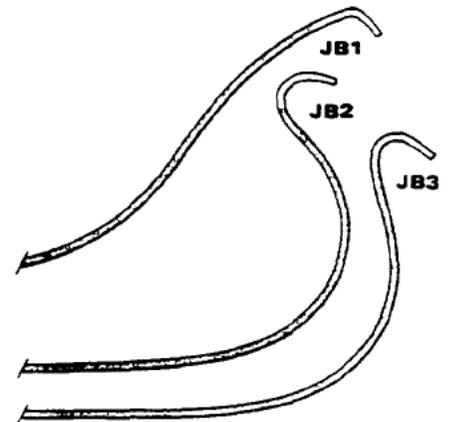
HINCK HEADHUNTER



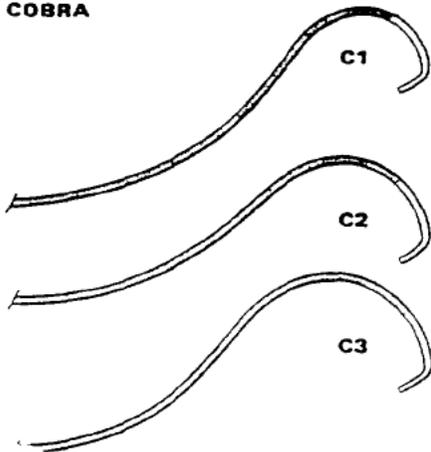
SIMMONS



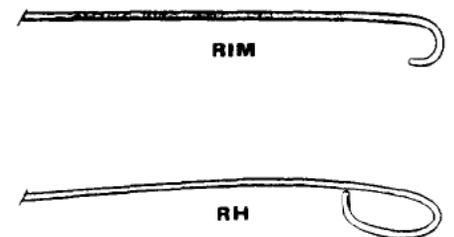
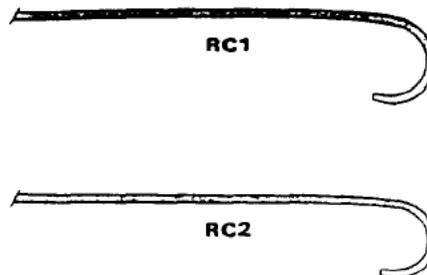
BENTSON-HANAFEE-WILSON



COBRA

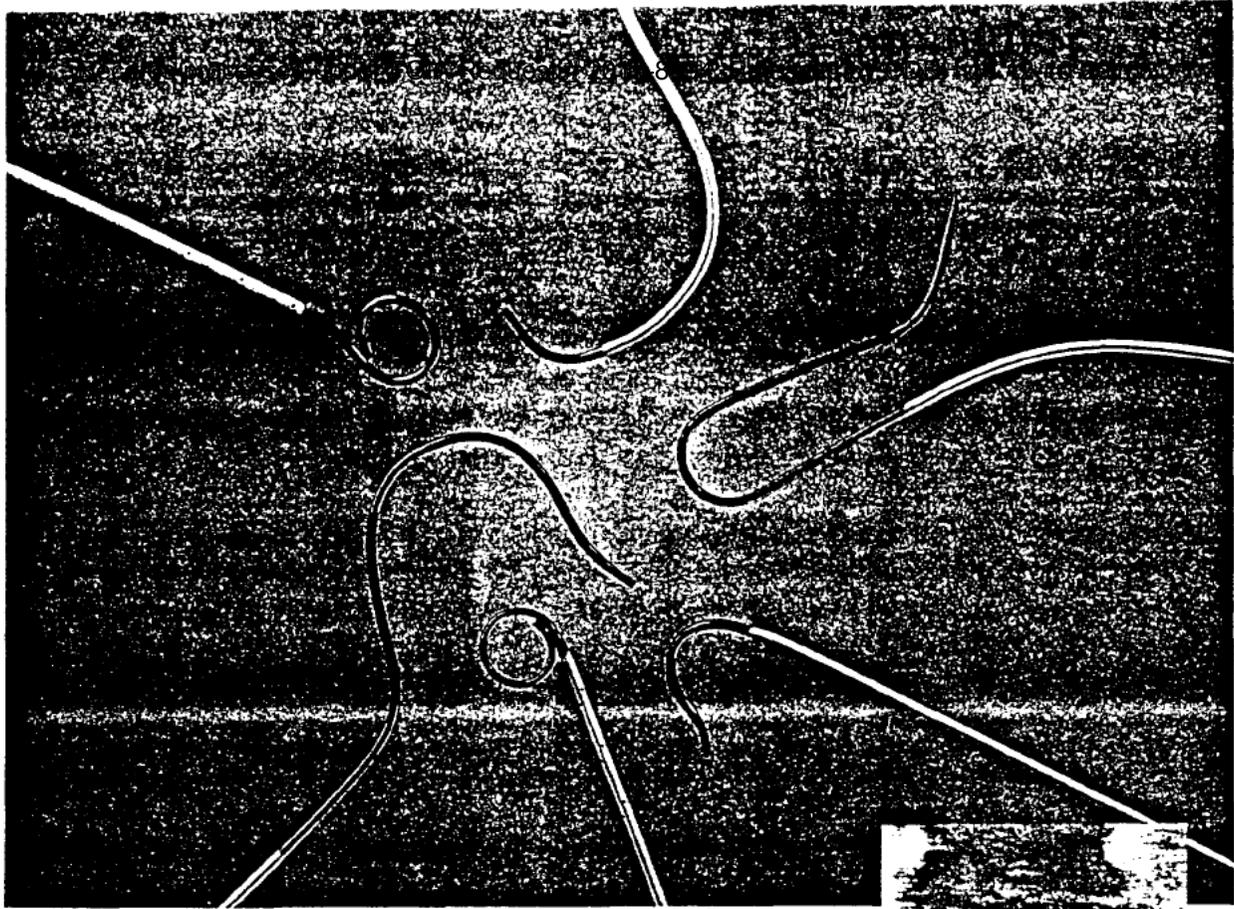


SELECTIVE AND SUPERSELECTIVE



OTHER TIP CONFIGURATIONS AVAILABLE UPON REQUEST.

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



SOFT-VU™ ANGIOGRAPHIC CATHETERS

*UNSURPASSED RADIOPACITY PROVIDES
FOR EXCELLENT VISUALIZATION*



Actual fluoroscopic image
of Soft-Vu™ 4F pigtail

- Fluoroscopically visible tip, even with a 4F catheter
- Soft and flexible tip reduces risk of vessel wall trauma
- Unique blending of tip and shaft material ensures integrity and strength
- Customized catheter shapes and lengths are available through our Custom Products Program
- Selective catheters available in both braided and non-braided designs

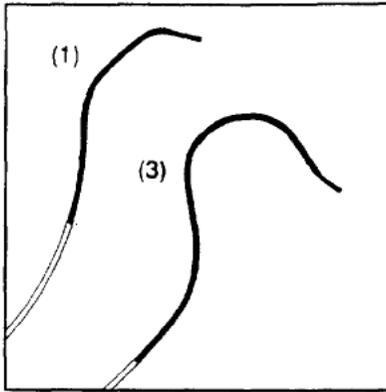
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SOFT-VU™ ANGIOGRAPHIC CATHETERS

ANGIO DYNAMICS™
Division of E-Z-EM, Inc.

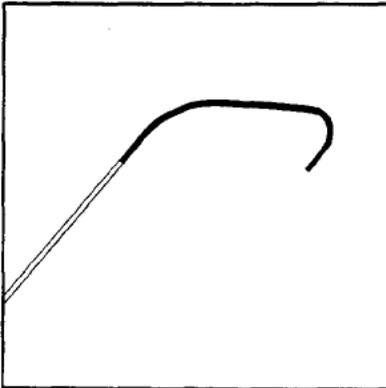
SOFT-VU™ ANGIOGRAPHIC CATHETERS

00-00050



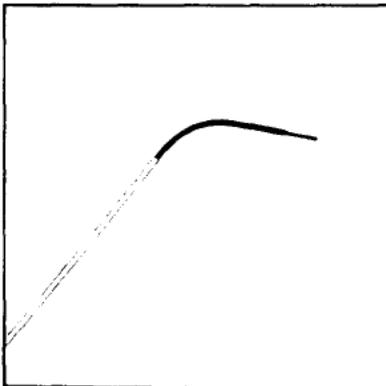
SELECTIVE CATHETERS: HEADHUNTER (NO SIDE HOLES)

Non-Braided Catalog No.	Braided Catalog No.	Description
10718301	10707501	HEADHUNTER (1) 4Fx100CM (.035 in.)
10718302	10707502	HEADHUNTER (3) 4Fx100CM (.035 in.)
10719501	10708901	HEADHUNTER (1) 5Fx100CM (.035 in.)
10719502	10708902	HEADHUNTER (3) 5Fx100CM (.035 in.)
10719503	10708903	HEADHUNTER (1) 5Fx100CM (.038 in.)
10719504	10708904	HEADHUNTER (3) 5Fx100CM (.038 in.)
10720701	10710301	HEADHUNTER (1) 6Fx100CM (.035 in.)
10720702	10710302	HEADHUNTER (3) 6Fx100CM (.035 in.)
10720703	10710303	HEADHUNTER (1) 6Fx100CM (.038 in.)
10720704	10710304	HEADHUNTER (3) 6Fx100CM (.038 in.)



SELECTIVE CATHETERS: RENAL (NO SIDE HOLES)

Non-Braided Catalog No.	Braided Catalog No.	Description
10718801	10708001	RENAL 4Fx65CM (.035 in.)
10720001	10709401	RENAL 5Fx65CM (.035 in.)
10720002	10709402	RENAL 5Fx65CM (.038 in.)
10721201	10710801	RENAL 6Fx65CM (.035 in.)
10721202	10710802	RENAL 6Fx65CM (.038 in.)



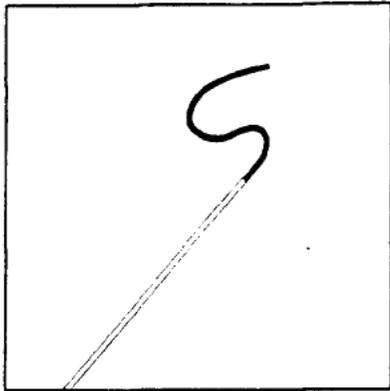
SELECTIVE CATHETERS: VERTEBRAL (2 SIDE HOLES)

Non-Braided Catalog No.	Braided Catalog No.	Description
10718101	10707301	VERTEBRAL 4Fx100CM (.035 in.)
10719301	10708701	VERTEBRAL 5Fx100CM (.035 in.)
10719302	10708702	VERTEBRAL 5Fx100CM (.038 in.)
10720501	10710101	VERTEBRAL 6Fx100CM (.035 in.)
10720502	10710102	VERTEBRAL 6Fx100CM (.038 in.)

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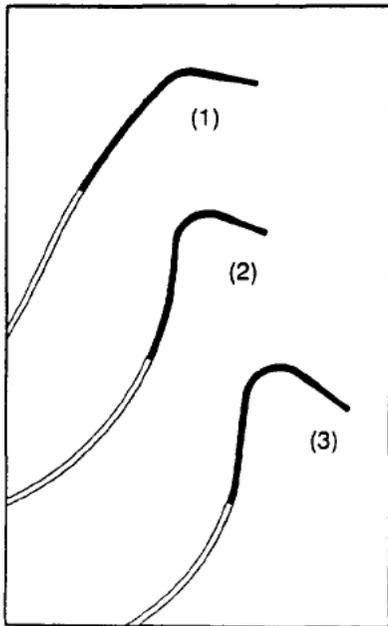
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SOFT-VU™ ANGIOGRAPHIC CATHETERS



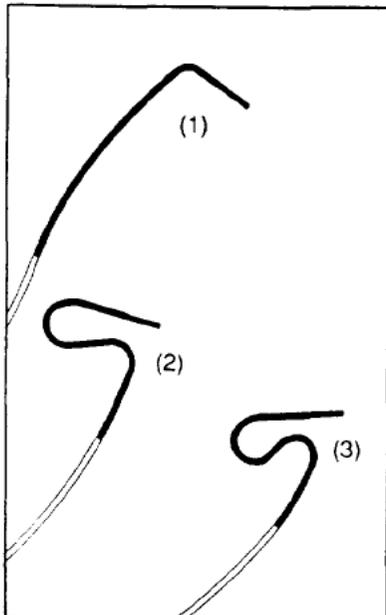
SELECTIVE CATHETERS: MANI (NO SIDE HOLES)

Non-Braided Catalog No.	Braided Catalog No.	Description
10718201	10707401	MANI 4Fx100CM (.035 in.)
10719401	10708801	MANI 5Fx100CM (.035 in.)
10719402	10708802	MANI 5Fx100CM (.038 in.)
10720601	10710201	MANI 6Fx100CM (.035 in.)
10720602	10710202	MANI 6Fx100CM (.038 in.)



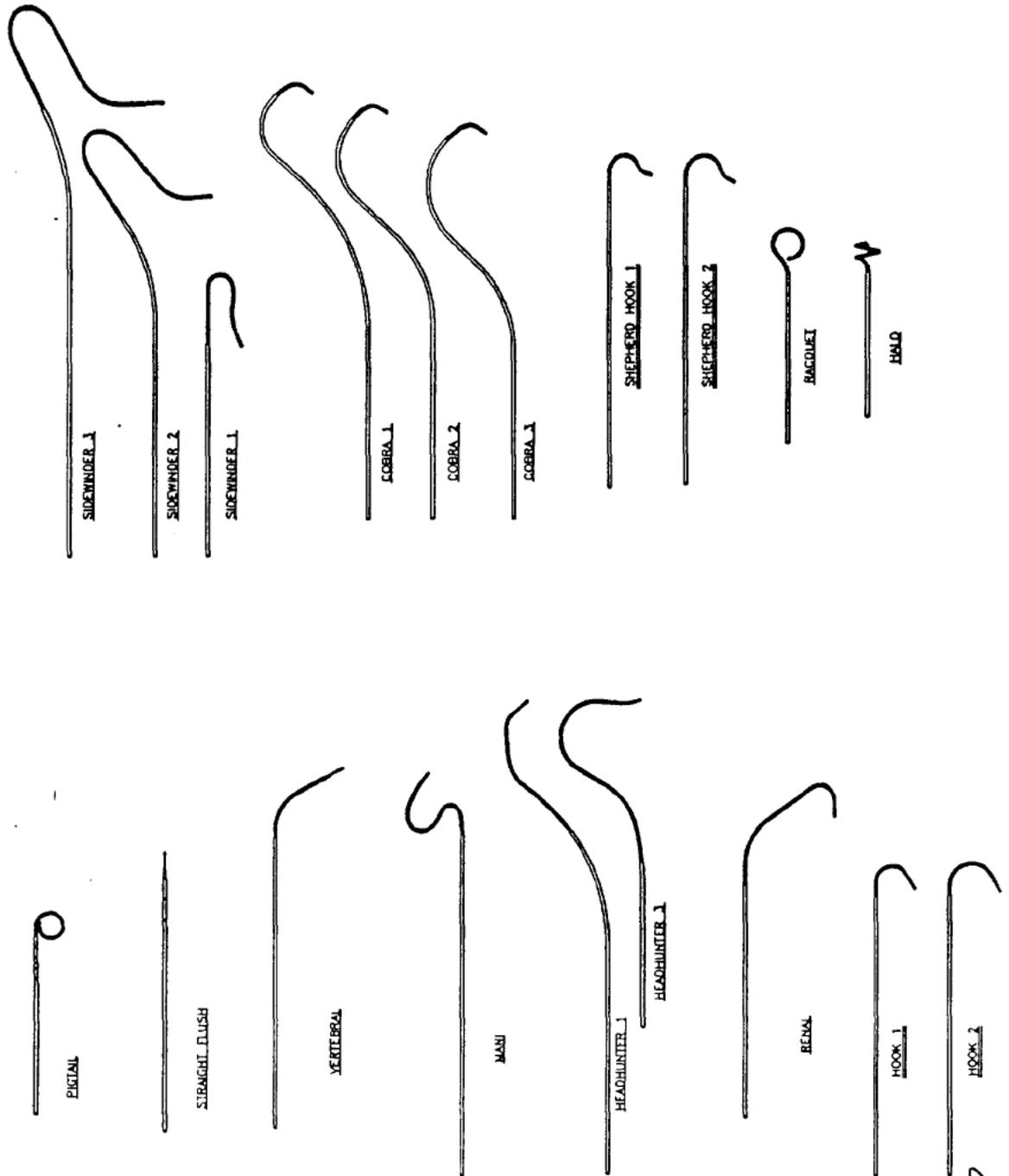
SELECTIVE CATHETERS: BENTSON (NO SIDE HOLES)

Non-Braided Catalog No.	Braided Catalog No.	Description
10719001	10708301	BENTSON (1) 4Fx100CM (.035 in.)
10719002	10708302	BENTSON (2) 4Fx100CM (.035 in.)
10719003	10708303	BENTSON (3) 4Fx100CM (.035 in.)
10720201	10709701	BENTSON (1) 5Fx100CM (.035 in.)
10720202	10709702	BENTSON (2) 5Fx100CM (.035 in.)
10720203	10709703	BENTSON (3) 5Fx100CM (.035 in.)
10720204	10709704	BENTSON (1) 5Fx100CM (.038 in.)
10720205	10709705	BENTSON (2) 5Fx100CM (.038 in.)
10720206	10709706	BENTSON (3) 5Fx100CM (.038 in.)
10721401	10711101	BENTSON (1) 6Fx100CM (.035 in.)
10721402	10711102	BENTSON (2) 6Fx100CM (.035 in.)
10721403	10711103	BENTSON (3) 6Fx100CM (.035 in.)
10721404	10711104	BENTSON (1) 6Fx100CM (.038 in.)
10721405	10711105	BENTSON (2) 6Fx100CM (.038 in.)
10721406	10711106	BENTSON (3) 6Fx100CM (.038 in.)



SELECTIVE CATHETERS: NEWTON (NO SIDE HOLES)

Non-Braided Catalog No.	Braided Catalog No.	Description
10719101	10708401	NEWTON (1) 4Fx100CM (.035 in.)
10719102	10708402	NEWTON (2) 4Fx100CM (.035 in.)
10719103	10708403	NEWTON (3) 4Fx100CM (.035 in.)
10720301	10709801	NEWTON (1) 5Fx100CM (.035 in.)
10720302	10709802	NEWTON (2) 5Fx100CM (.035 in.)
10720303	10709803	NEWTON (3) 5Fx100CM (.035 in.)
10720304	10709804	NEWTON (1) 5Fx100CM (.038 in.)
10720305	10709805	NEWTON (2) 5Fx100CM (.038 in.)
10720306	10709806	NEWTON (3) 5Fx100CM (.038 in.)
10721501	10711201	NEWTON (1) 6Fx100CM (.035 in.)
10721502	10711202	NEWTON (2) 6Fx100CM (.035 in.)
10721503	10711203	NEWTON (3) 6Fx100CM (.035 in.)
10721504	10711204	NEWTON (1) 6Fx100CM (.038 in.)
10721505	10711205	NEWTON (2) 6Fx100CM (.038 in.)



ANGIODYNAMICS™
 GLENS FALLS, N.Y. 12801 Division of I-I-DL, Inc.

SOFTTIP
 CATHETER SHAPES

5

82

DATE: January 5, 1993

TO: Marlene Wright

FROM: Lawrence Hu *Lawrence Hu*

SUBJECT: CES Envoy Guiding Catheter / 510(k) Submission Testing

ATT:

1. ENVOY Guiding Catheter Schematic
2. Cordis QCOP 05-331
3. Cordis QCOP 21-260



OBJECTIVE

The following report summarizes the testing performed for the 510(k) submission for the CES 6F "Envoy" guiding catheter. The testing is intended to show the equivalence of the Envoy design and performance to existing FDA cleared devices.

BACKGROUND

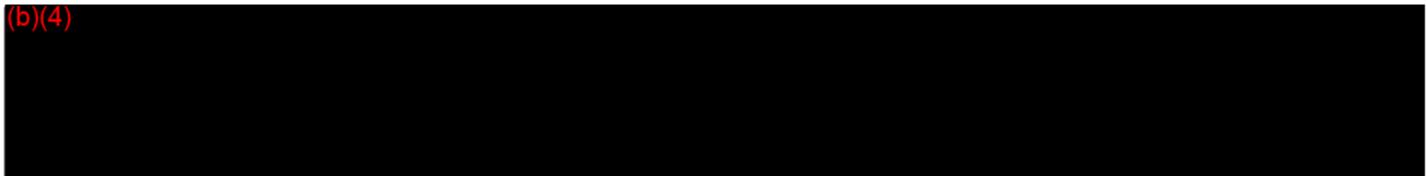
The CES Envoy guiding catheter is a modification of the Cordis 6F guiding catheter. The distal eight inches of the catheter has been modified to be softer for use in neurovascular and peripheral procedures. The design changes and process changes made to the catheter are minor and the testing is intended to support that the safety and integrity of the CES 6F guiding catheter are equivalent to the Cordis 6F guiding catheter. The testing is also intended to show that for the same degree of access provided by the 5.0F Super Torque diagnostic catheters, the CES guiding catheter provides the equivalent tip flexibility for atraumatic access and torque response for maneuverability.

The tests conducted were:



The testing performed for (b)(4) used a Cordis 5.0F Super Torque diagnostic catheter for comparison and the other tests used a Cordis 6F Brite Tip guiding catheter for comparison.

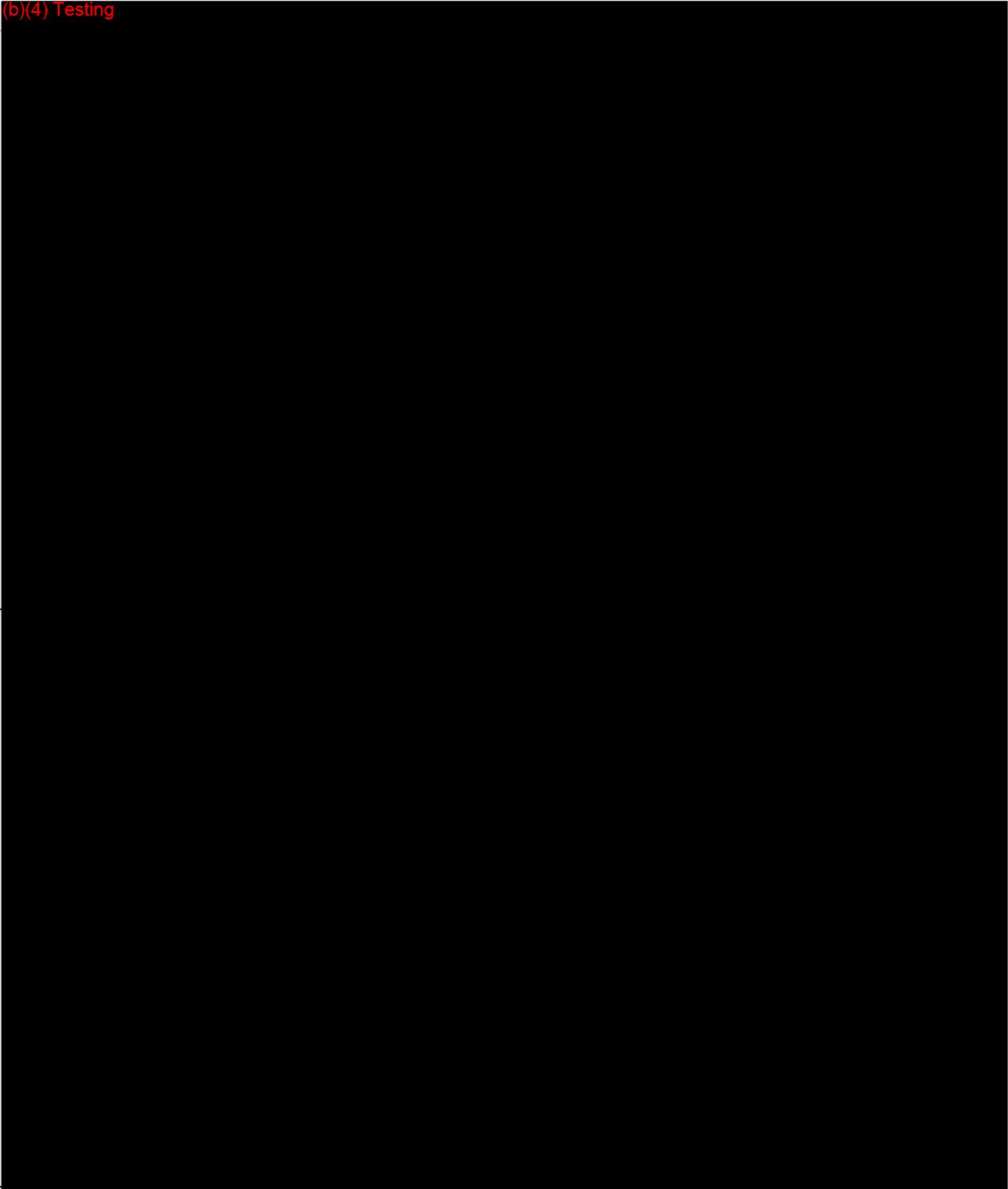
The testing was performed on sterile product:



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TESTING METHODS AND RESULTS

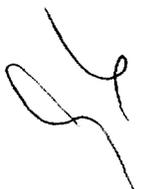
(b)(4) Testing

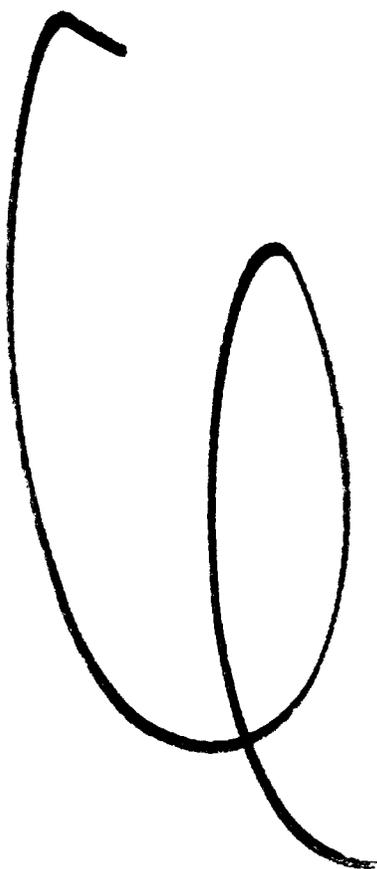


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SUMMARY

The testing in this report covers the important safety and performance issues dealing with the catheter. In no case did the testing show that the CES 6F Envoy differs significantly from the other catheters in terms of performance characteristics.







Cordis Endovascular Systems, Inc.
14740 N.W. 60th Avenue
Miami Lakes, FL 33014 USA
(305) 824-8600
(305) 824-8610 Fax

Material Certification

On behalf of Cordis Endovascular Systems, we hereby certify that the materials used in the ENVOY Guiding Catheter are the identical material/chemical formulation as the materials used in the Cordis 6F PTCA Guiding Catheters (K915374, concurrence on 2-11-92).

(b)(6)

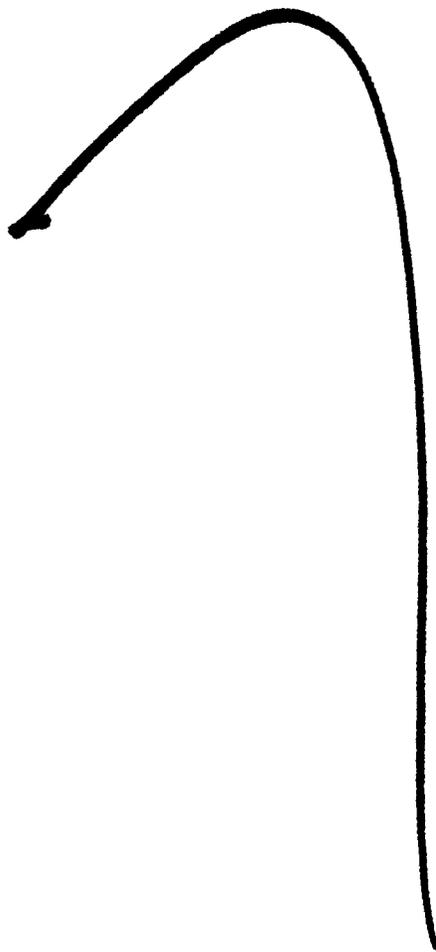
Manager, Regulatory Affairs and
Clinical Research

1/12/94
Date

(b)(6)

(b)(6)
Director, Manufacturing Operations

1-12-94
Date



Handwritten mark

Records processed under FOIA Request # 2015-8094; Released by CDRH on 12-10-2015

Ms. Katherine Trevisol
Associate Manager
Clinical Research
Cordis Corporation
P.O. Box 025700
Miami, Florida 33102-5700

Re: E915836
Cordis S.O French Super
Torque Catheters
Regulatory Class II
Dated: December 23, 1991
Received: December 24, 1991

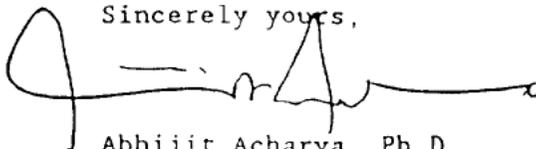
Dear Ms. Trevisol:

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 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 (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. 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, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. 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 on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. 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,



Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FEB 14 1992

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850Mr. Ralph Jugo
Associate Manager
Clinical Research
Cordis Corporation
P.O. Box 025700
Miami, Florida 33102-5700Re: K915374
Cordis 6 French 0.062" I.D.
PTCA Guiding Catheter
Regulatory Class: II
Dated: November 27, 1991
Received: November 29, 1991

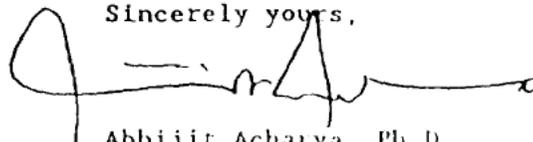
Dear Mr. Jugo:

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 registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

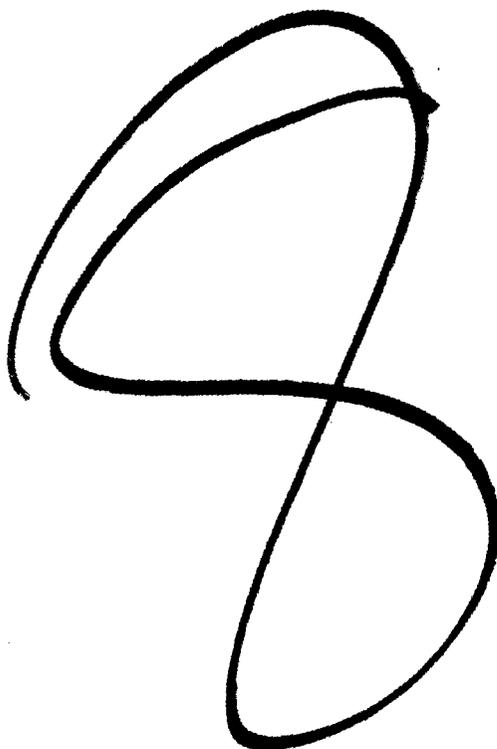
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, 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, or other Federal laws or regulations.

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Sincerely yours,



Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



A small, handwritten signature or initials in the bottom right corner of the page, written in black ink.

Summary of Safety and Effectiveness

Pursuant to Section 513 (i)

of the Food, Drug and Cosmetic Act

I. General Provisions

Common or Usual Name: Guiding Catheter

Proprietary Name: ENVOY™ Guiding Catheter

II. Name of Predicate Devices

Cordis Corporation PTCA 6F Guiding Catheter 510 (k) # K915374
Cordis 5.0 French Super Torque Catheters 510 (k) #K915836

III. Classification

Class II

IV. Performance Standards

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

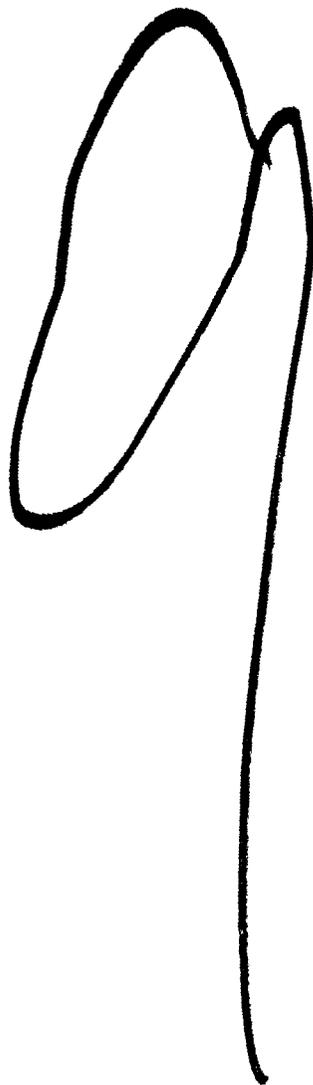
The ENVOY Guiding Catheters are designed for the intravascular introduction of interventional/diagnostic products in the peripheral and neurovascular system.

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the ENVOY Guiding Catheters.

VII. Summary of Substantial Equivalence

The ENVOY Guiding Catheters are similar in its basic design, construction, indication for use and performance characteristics to other commercially available infusion catheters.



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**FDA Meeting Minutes
October 26, 1993**

Attendees:

Lynne Reamer - Associate Director for Pacing & Neurological Devices, FDA
Bob Munzner - Chief of Neurology Branch, FDA
Lev Keely - Reviewer, FDA
John Glass - Reviewer, FDA

Ann Costello - Reviewer, FDA

(b)(6) - President, CES

(b)(6) - Medical Consultant, CES

(b)(6) - Medical Consultant, CES

(b)(6) - Manager Clinical Research, Cordis

(b)(6) - Manager Regulatory Affairs and Clinical Research

Objectives:

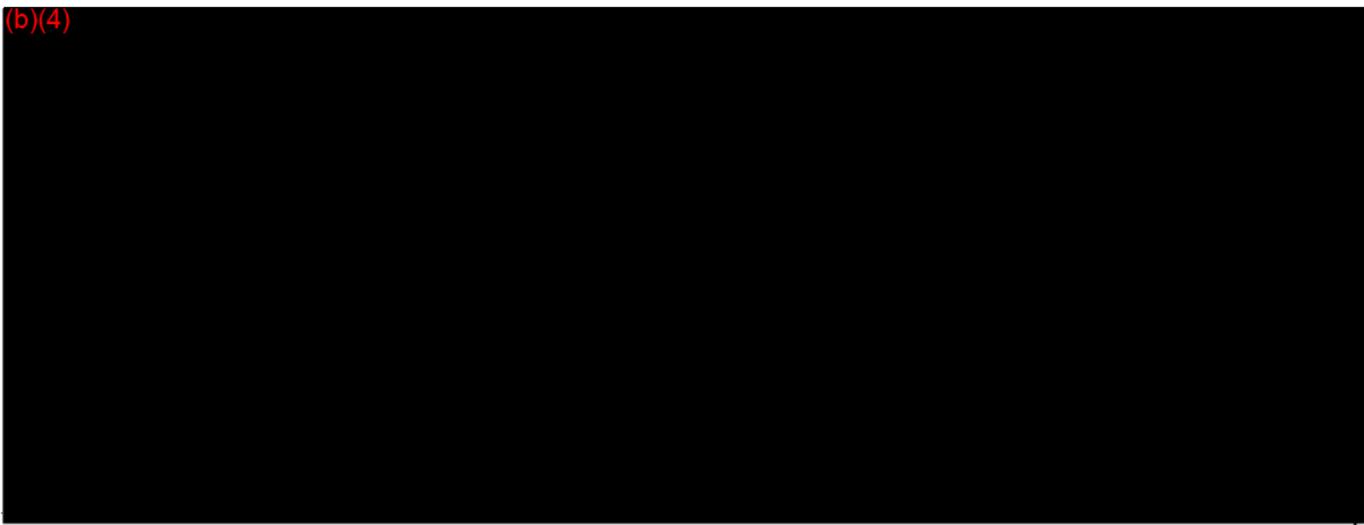
To develop a positive working relationship with the Neurology Branch.
To determine the regulatory requirements for several Neuroradiology products.
To review proposed response to Illusion Guidewire deficiency letter.

Regulatory Strategy:

- * We will provide the same *in-vitro* testing for the Infusion Catheter and Guiding Catheter as will be provided for the Guidewire 510 (k) submission.

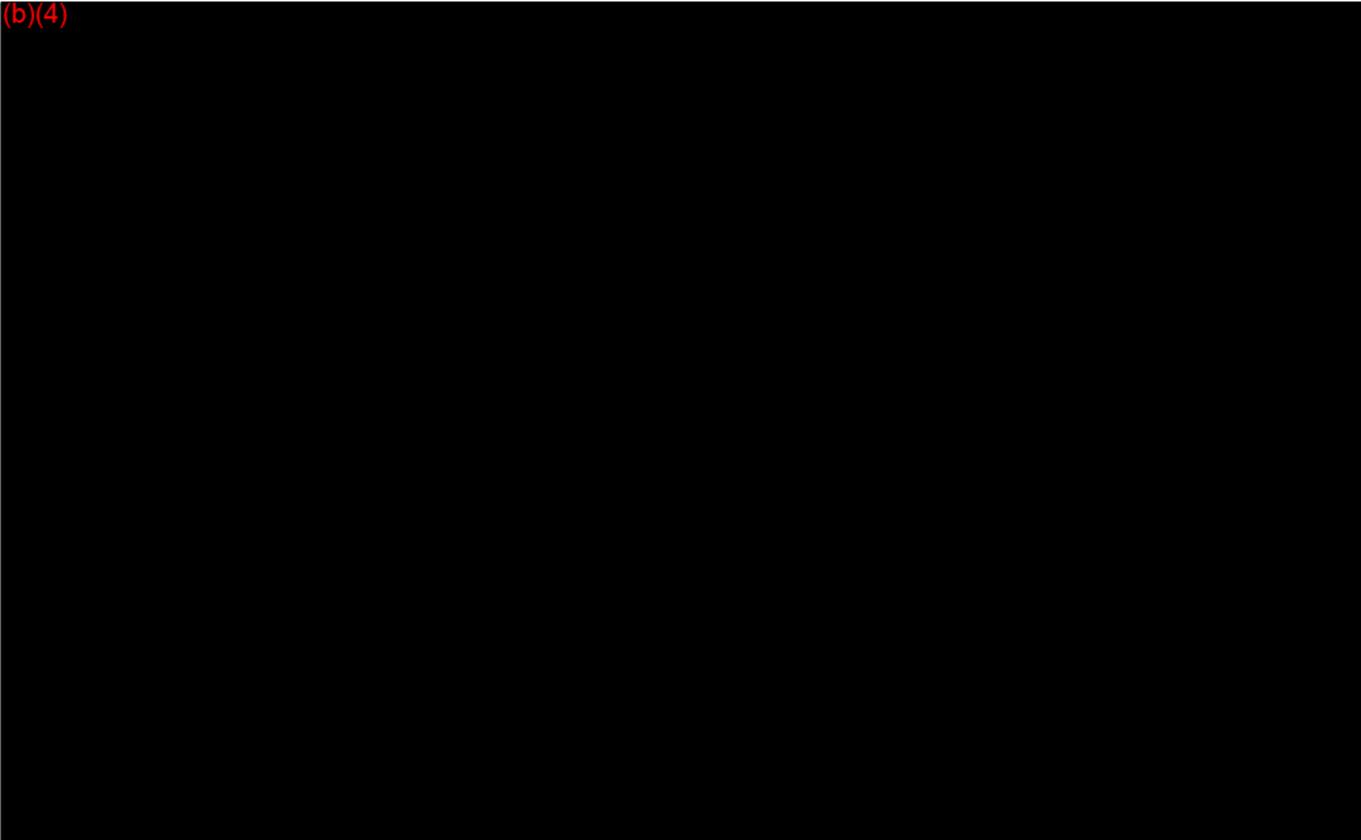
Summary of Proposed Response to Deficiency Letter:

(b)(4)



107

(b)(4)



The meeting concluded on a positive note and both objectives were met.



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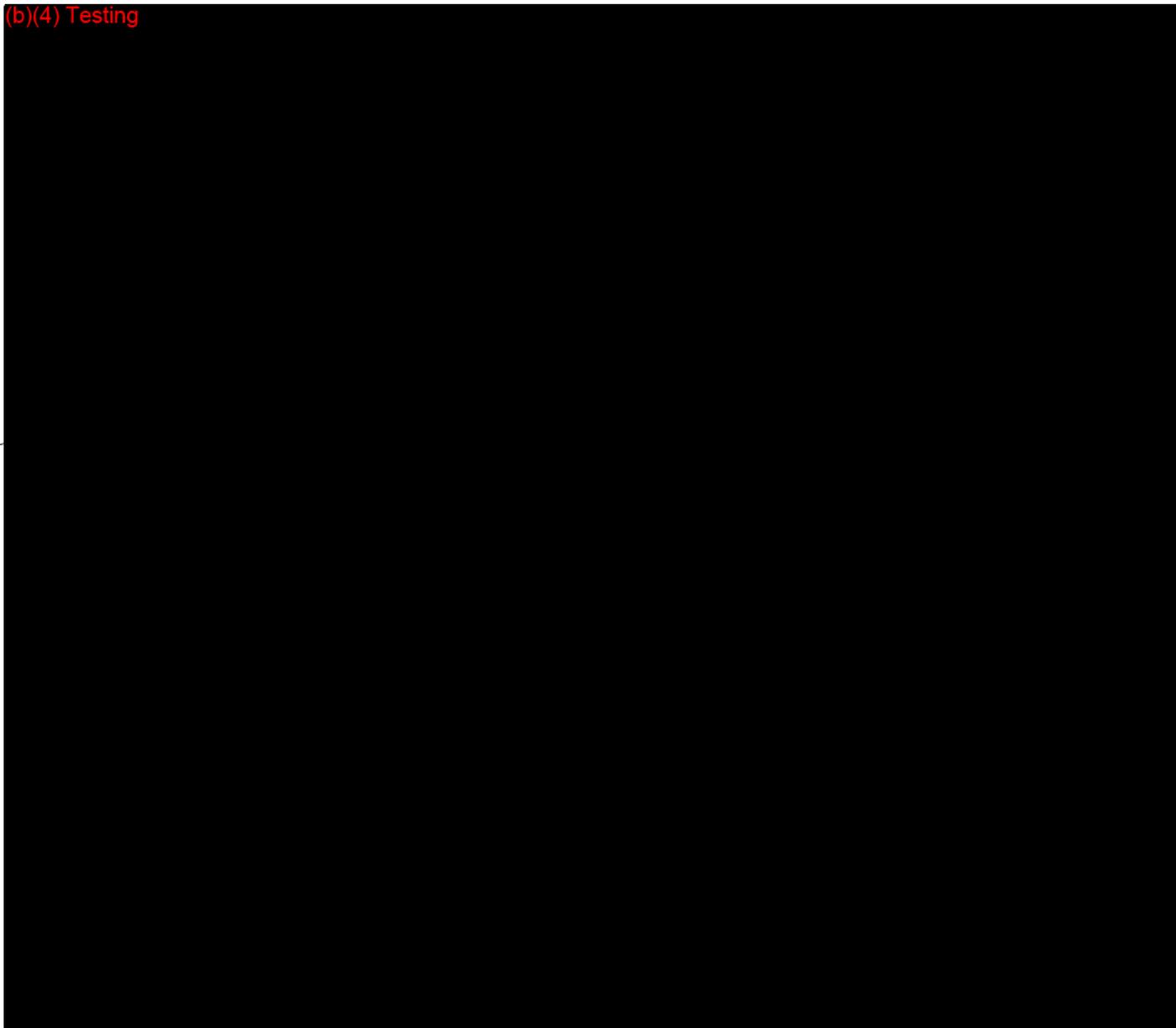
TO: ENVOY Guiding Catheter File

FROM: Marlene Wright *msw*

DATE: January 5, 1994

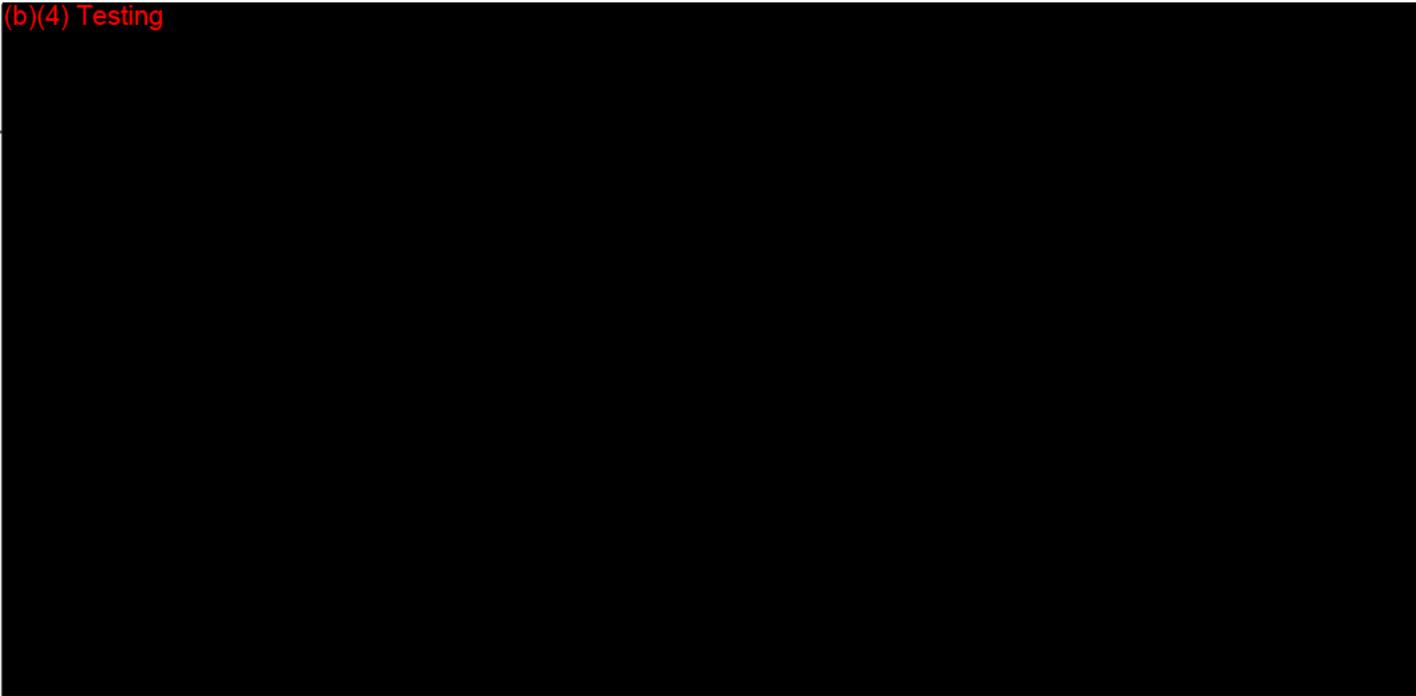
SUBJECT: (b)(4) Testing of the ENVOY Guiding Catheter

(b)(4) Testing



108

(b)(4) Testing



CONCLUSION

The test results demonstrate that the ENVOY Guiding Catheters performed comparable to the current products being marketed for use in the neurovascular system.



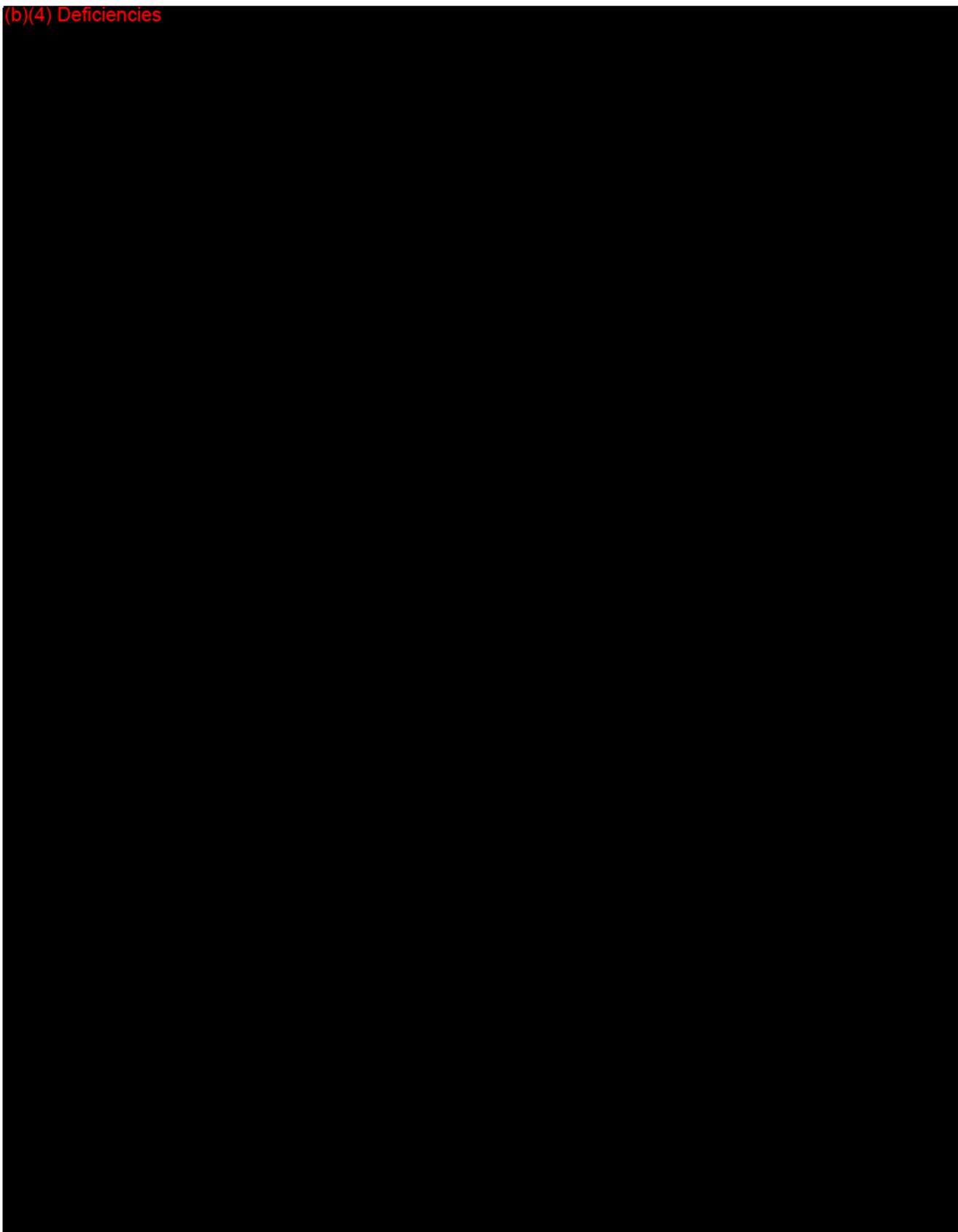
11

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00-00078

CONFIDENTIAL

(b)(4) Deficiencies



-- -- CONFIDENTIAL -- --

~~000002~~

00-00079

(b)(4) Deficiencies



000003

