DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 1997

Mr. John C. Heinmiller
Official Correspondent
Diag Corporation
14901 DeVeau Place
Minnetonka, Minnesota 55345-2126

Re: K964518
Fast-Cath™ Transseptal Catheter Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: February 13, 1997
Received: February 14, 1997

Dear Mr. Heinmiller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in

regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

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

Enclosure

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510(k) Number (if known): K964518

Device Name: Fast-Cath™ Transseptal Catheter Introducer

Indications for Use:

Daig Fast-Cath™ Transseptal Catheter Introducers are designed for use when a procedure involves introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

(Division Sign
Division of Ca
and Neurologica
510(k) Number K964518

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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510(K) ROUTE SLIP

510(k) NUMBER K964518 PANEL CV DIVISION DCRND BRANCH ICDG

TRADE NAME FAST-CATH TRANSSEPTAL CATHETER INTRODUCER

COMMON NAME TRANSSEPTAL CATHETER INTRODUCER

PRODUCT CODE ___

APPLICANT DAIG CORP.
SHORT NAME DAIG
CONTACT JOHN C HEINMILLER
DIVISION
ADDRESS 14901 DEVEAU PLACE
MINNETONKA, MN 553452126
PHONE NO. (612) 933-4700 FAX NO. (612) 930-9481

MANUFACTURER DAIG CORP. REGISTRATION NO. 2182269

DATE ON SUBMISSION 24-OCT-96 DATE DUE TO 510(K) STAFF 08-JAN-97

DATE RECEIVED IN ODE 25-OCT-96 DATE DECISION DUE 23-JAN-97

DECISION __ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	13-FEB-97	14-FEB-97	30-APR-97	15-MAY-97	

CORRESPONDENCE	SENT	DUE BACK	
C001	22-JAN-97	21-FEB-97	HOLD LETTER

Is this 510(k) identified as a Class III device ____YES ____NO

SE

MAY 14 1997

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service — Food And Drug Administration

May 6, 1997

Memorandum

From: Reviewer(s) - Name(s) Kimberly Boone Peters

Subject: 510(k) Number K964518/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☑ Is substantially equivalent to marketed devices. See attached review
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☑NO
Is this device subject to the Tracking Regulation?	☐YES	☑NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☑NO
Is this a prescription device?	☑YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☑NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☑Enclosed (Original submission, section 3) (required for originals received 3-14-95 and after)

☐A 510(k) summary OR ☑A 510(k) statement (original submission, section 4)

☐ The required certification and summary for class III devices NA

☑ The indication for use form (required for originals received 1-1-96 and after) (9/13/97 submission, Exhibit C)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☑ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: 74 DYB Class II

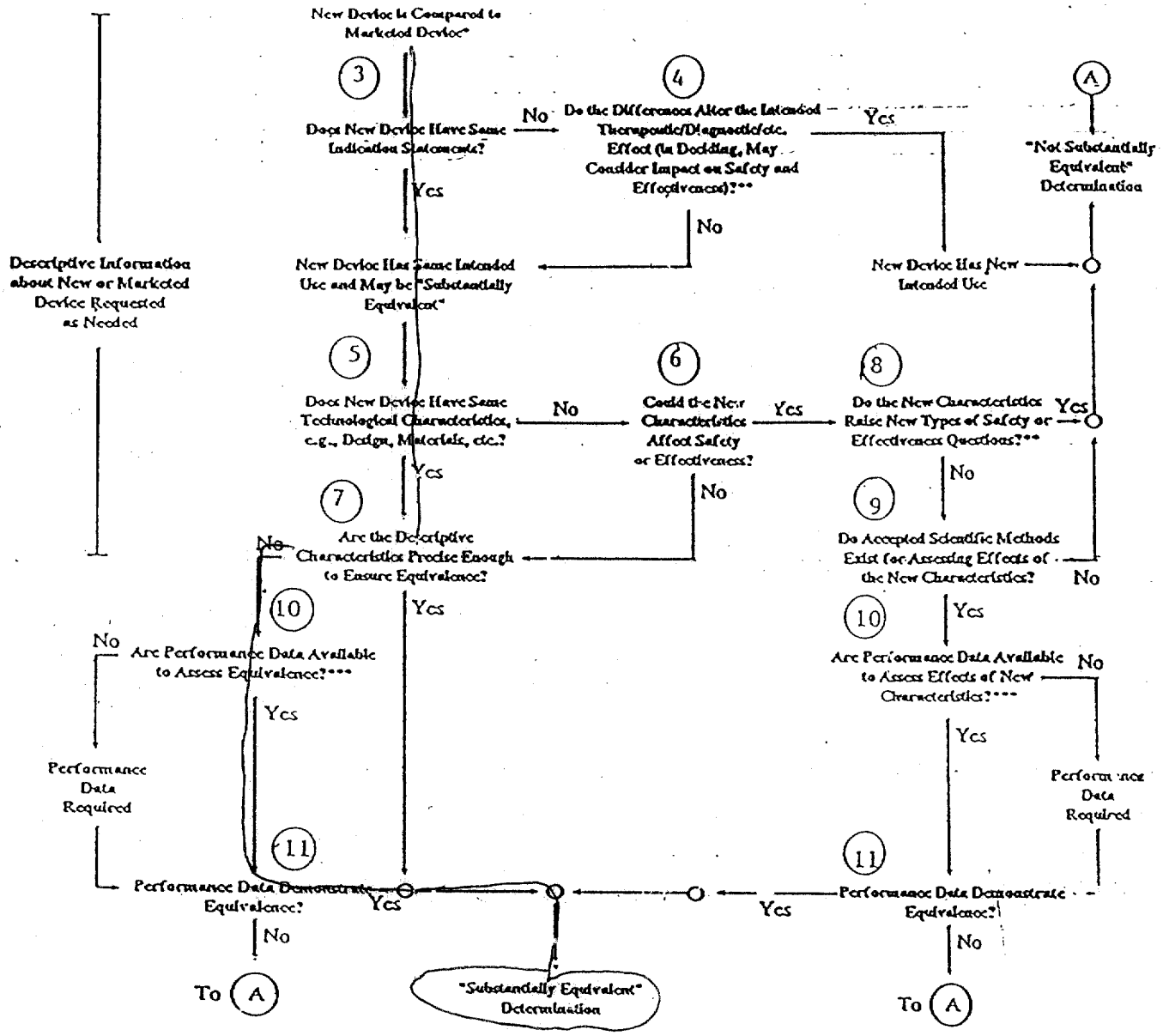
Additional Product Code(s) with panel (optional): _____

Review: J. Jamieson — Signatory Reviewer (~~Branch Chief~~) — FC06 (Branch Code) — 5/13/97 (Date)

Final Review: Tena A. Ru for Thomas J. Callahan, Ph.D — (Division Director) — 5/13/97 (Date)

Revised: 11-20-96

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Avenue
Rockville, MD 20850

MEMORANDUM TO THE RECORD
Premarket Notification [510(k)] Review
K964518/S1

DATE: May 6, 1997
FROM: Kimberly Bowie Peters

OFFICE: HFZ-450
DIVISION: DCRND/ICDG

COMPANY NAME: Daig Corporation
DEVICE NAME: Fast-Cath Transseptal Catheter Introducer

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. **REASON FOR SUBMISSION:**
This premarket notification submission addresses the addition of curve styles to the currently marketed line of the Fast-Cath Transseptal Catheter Introducer (K911883).

2. **INTENDED USE:**
The Fast-Cath Transseptal Catheter Introducer is intended for use when introducing various cardiovascular catheters into the left side of the heart through the interartial septum.

The currently marketed Fast -Cath Transseptal Catheter Introducer cleared in K911883 features the same indications for use statement.

3. **DEVICE DESCRIPTION:**

A. **Life-supporting or life sustaining:** No
B. **Implant (short-term or long term):** No
C. **Is the device sterile?** Yes
If yes, is sterility information provided? Yes (Original submission section 10 & 2/13/97 submission)

The submission indicates that the catheter will be sterilized (b)(4) The sterilization cycle is validated using an (b)(4) method established per guidelines in the ANSI/AAMI standard. The sterility assurance level that will be claimed for the device is 10[redacted]. The maximum levels of (b)(4) (b)(4) [redacted]. Test results supporting compliance to these levels are included in Exhibit F. The information does indicate that pyrogenicity testing will be performed per USP XXII on each sterilized lot.

The packaging for the device consists of a formed (b)(4) tray (b)(4) (b) into a labeled (b)(4) (b)(4) pouch. The submission indicates that this same device packaging configuration has been used for Daig devices over 5 years. Shelf life testing information supporting a 5 year shelf life was provided in K892528; however, a 3 year shelf life will be claimed. The predicate device submission (K911883) also references the shelf life testing information included in K892528.

D. **Is the device for single use?** Yes (section 7)
E. **Is the device for prescription use?** Yes

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If yes, is prescription labeling included? Yes (2/13/97 submission, Exhibit D)

F. **Is the device for hospital, home, or portable use?** Hospital
Is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary? NA, device is a catheter introducer.

G. **Does the device contain drug or biological product as a component?** No

H. **Is this device a kit?** No
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? NA

I. **Soft-ware driven:** No
Estimated level of concern: (Major, Moderate, Minor)? NA
Has the firm provided hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices? NA
Software version: NA

J. **Electrically Operated:** No
If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? NA

K. **Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):** None
If applicable, has test data been provided to demonstrate conformance (protocol, data, and results) NA

L. **Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preAmendment status:**
Fast-Cath Transseptal Catheter Introducer by Daig (K911883)

M. **Submission provides comparative specifications:** Yes[a]
comparative <u>in vitro</u> data: Yes[b]
animal testing: No
clinical testing: No
biocompatibility testing: Yes[c]

[a]Section 6 includes catalogue information for predicate devices. Additional comparative information is included in Exhibit B of the February 13, 1997, submission.

[b]Section 12 of the submission includes performance testing information. The testing information includes (b)(4) (b)(4) . The test samples included (b)(4) he conclusion section indicates that (b)(4)

(b)(4) testing was performed on (b)(4) (b)(4)

During t(b)(4) test, the (b)(4) (b)(4)

[c]The premarket notification (section 5) indicates that device materials and manufacturing processes are the same as those used in the currently marketed Daig Fast-Cath Transseptal Catheter Introducer (K911883). Biocompatibility testing information is included in section 9 of the submission. This testing information includes (b)(4)

8

(b)(4)

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

This premarket notification submission addresses the addition of curve styles to the currently marketed line of Fast-Cath Transseptal Catheter Introducer (K911883). Drawings of the available curve styles are included in Exhibit A of the February 13, 1997, submission. The Fast-Cath Transseptal Catheter Introducer is intended for use when introducing various cardiovascular catheters into the left side of the heart through the interartial septum.

The introducer set consists of a radiopaque sheath and a dilator, each with curved distal portions to accommodate positioning in the cardiac anatomy. Exhibit C of the February 13, 1997, submission identifies the introducer sets that will be available. The introducer sheath is fitted with a hemostasis valve to (b)(4) (b)(4). The hemostasis valve is the same as that featured in the predicate Fast-Cath. A sideport with 3-way stopcock is provided for (b)(4).

Two curve styles (AMAS 1-2 and AMAS 3-4) will also be available in an 11 Fr sheath size and will not be packaged with a dilator. The currently marketed Catheter Introducer Sheath by Applied Vascular Devices (K890766) features a 10Fr catheter size with an end that expands to 21Fr.

O. Request for additional information:

The following information was requested in the January 22, 1997, hold letter to the firm. The firm's response is included in the February 13, 1997, submission.

(b)(4)

Response: (b)(4)

2. (b)(4)

Response:

3. (b)(4) *the*

Response:

(b)(4)

Response: (b)(4)

9

(b)(4)

Response
(b)(4)

d. (b)(4)

Response: (b)(4)

4. (b)(4)

Response: (b)
(b)(4)

(b)(4)

5. (b)(4)

Response:
(b)(4)

Response:
(b)(4)
(b)(4)

Response: (b)(4)
(b)(4)

6. (b)(4)

Response: (b)(4)

P. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? No
If not, does the submission include a certification that such information will be made available to interested persons upon request? Yes (section 4)

Does the submission include the truthful and accurate statement? Yes (section 3)

Does the submission include the indications for use form? Yes (2/13/97 submission, Exhibit G)

If the device is substantially equivalent to a Class III device, does the submission include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) 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? NA

Q. 510(k) Flow Chart

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

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS AS NEEDED (DELETE QUESTIONS WHICH ARE NOT APPLICABLE)

1. **IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE PRODUCT IS NOT A DEVICE.** The product under review in this file is a device.

2. **IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K).** This device is subject to a 510(k).

3. **IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION.** The Fast-Cath Transseptal Catheter Introducer is intended for use when introducing various cardiovascular catheters into the left side of the heart through the interartial septum. The currently marketed Fast -Cath Transseptal Catheter Introducer cleared in K911883 features the same indications for use statement.

4. **IF THE ANSWER TO QUESTION 4 IF YES OR NO, EXPLAIN WHY THERE IS/IS NOT A NEW EFFECT OR SAFETY EFFECTIVENESS ISSUE.** NA

5. **IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS.** [redacted] (b)(4) [redacted]. This premarket notification submission addresses the addition of curve styles to the currently marketed line of the Fast-Cath Transseptal Catheter Introducer (K911883).

6. **IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS.** NA

7. **IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH.** (b)(4) [redacted] (b)(4) [redacted]

8. **IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW.** NA

9. **IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED.** NA

10. **IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED.** (b)(4) [redacted]

11. **IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT.** (b)(4) [redacted].

R. **RECOMMENDATION:**
I believe that this device is equivalent to: 74 DYB

Classification should be based on:

870.1340 Catheter Introducer **Class:** II

Kimberly Bowie Peters

Kimberly Bowie Peters, May 6, 1997
Division of Cardiovascular, Respiratory, & Neurological Devices

Concur Johnelson 5/13/97

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

February 14, 1997

DAIG CORP.
14901 DEVEAU PLACE
MINNETONKA, MN 55345
ATTN: JOHN C. HEINMILLER

510(k) Number: K964518
Product: FAST-CATH
TRANSSEPTAL
CATHETER
INTRODUCER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

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DAIG
a St. Jude Medical Company

February 13, 1997

Hand Delivered via Federal Express P-1

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

RE: **Document Control No. K964518/A1**
Fast-Cath™ Transseptal Catheter Introducer
Establishment Reg. No. 2182269

Dear Ms. Peters:

The following information is being submitted in response to your letter dated January 22, 1997 regarding Document Control No. K964518 FAST-CATH™ TRANSSEPTAL CATHETER INTRODUCER.

FDA Item 1.

(b)(4) [redacted]

Daig Response to FDA Item 1.

(b)(4) [redacted]

FDA Item 2.

(b)(4) [redacted]

Daig Response to FDA Item 2.

(b)(4) [redacted]

FDA Item 3.

(b)(4) [redacted]

Daig Response to FDA Item 3a.

(b)(4) [redacted]

(b)(4) [redacted]

15

(b)(4)

[redacted]

Daig Response to FDA Item 3b.

(b)(4)

[redacted]

Daig Response to FDA Item 3c.

(b)(4)

[redacted]

16

Daig Response to FDA Item 3d.

(b)(4) [redacted]

FDA Item 4.

(b)(4) [redacted]

Daig Response to FDA Item 4a.

(b)(4) [redacted]

Daig Response to FDA Item 4b.

(b)(4) [redacted]

Daig Response to FDA Item 4c.

(b)(4) [redacted]

(b)(4) [redacted]

Daig Response to FDA Item 4d.

(b)(4) [redacted]

Daig Response to FDA Item 4e.

(b)(4) [redacted]

FDA Item 5.

(b)(4) [redacted]

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Daig Response to FDA Item 5a.

(b)(4)

[redacted]

Daig Response to FDA Item 5b.

(b)(4)

[redacted]

Daig Response to FDA Item 5c.

(b)(4) [redacted]

FDA Item 6.

(b)(4) [redacted]

Daig Response to FDA Item 6.

(b)(4) [redacted]

Sincerely,

DAIG CORPORATION

John C. Heinmiller
Official Correspondent

Enclosures (2)

Exhibit A
Document Control No. K964518

Detailed Description of the Fast-Cath™ Transseptal Catheter Introducer

Included as Exhibit A are engineering drawings, with the component parts and materials labeled, and all specific dimensions identified.

Daig has included a separate drawing for each transseptal catheter introducer to be marketed.

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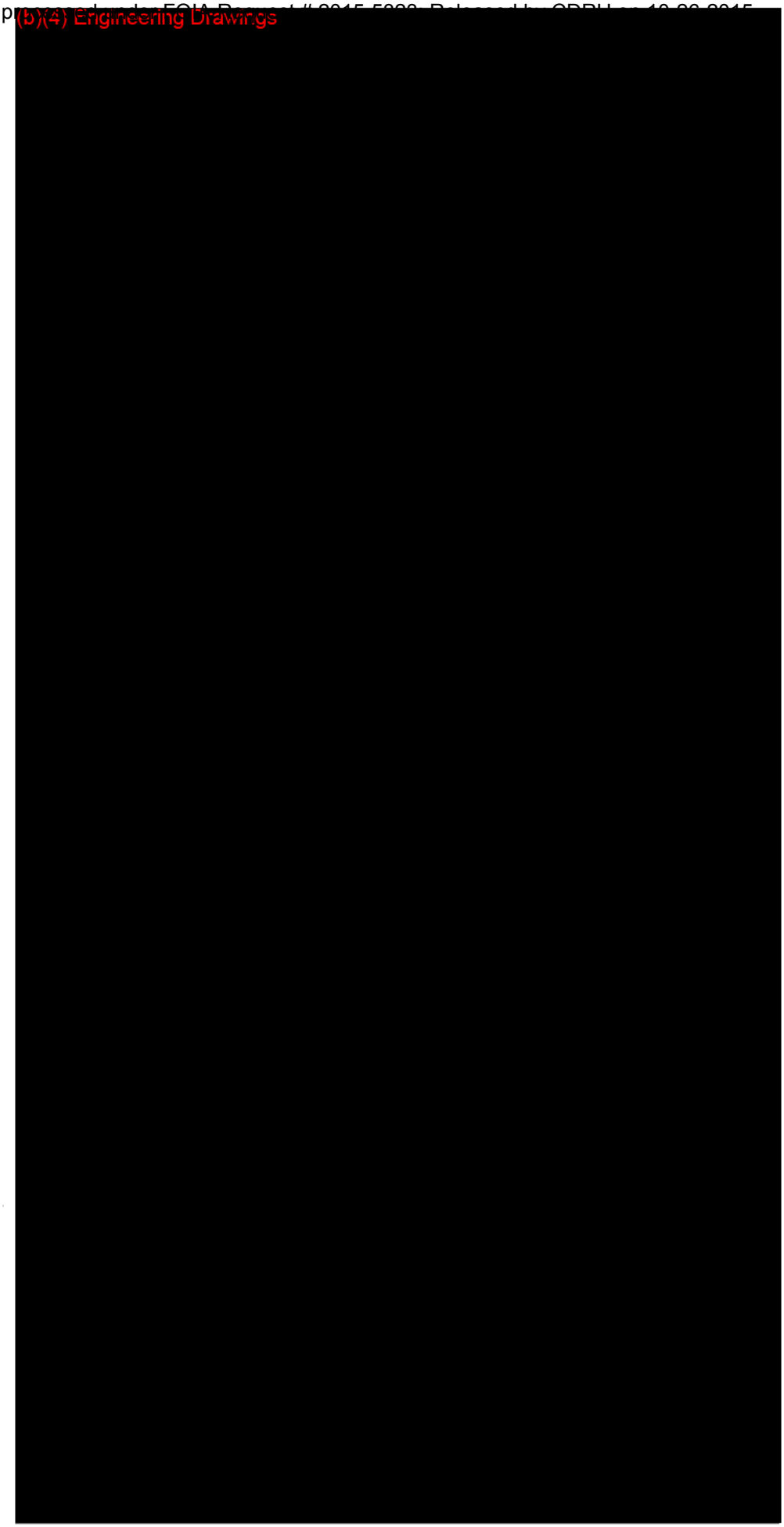
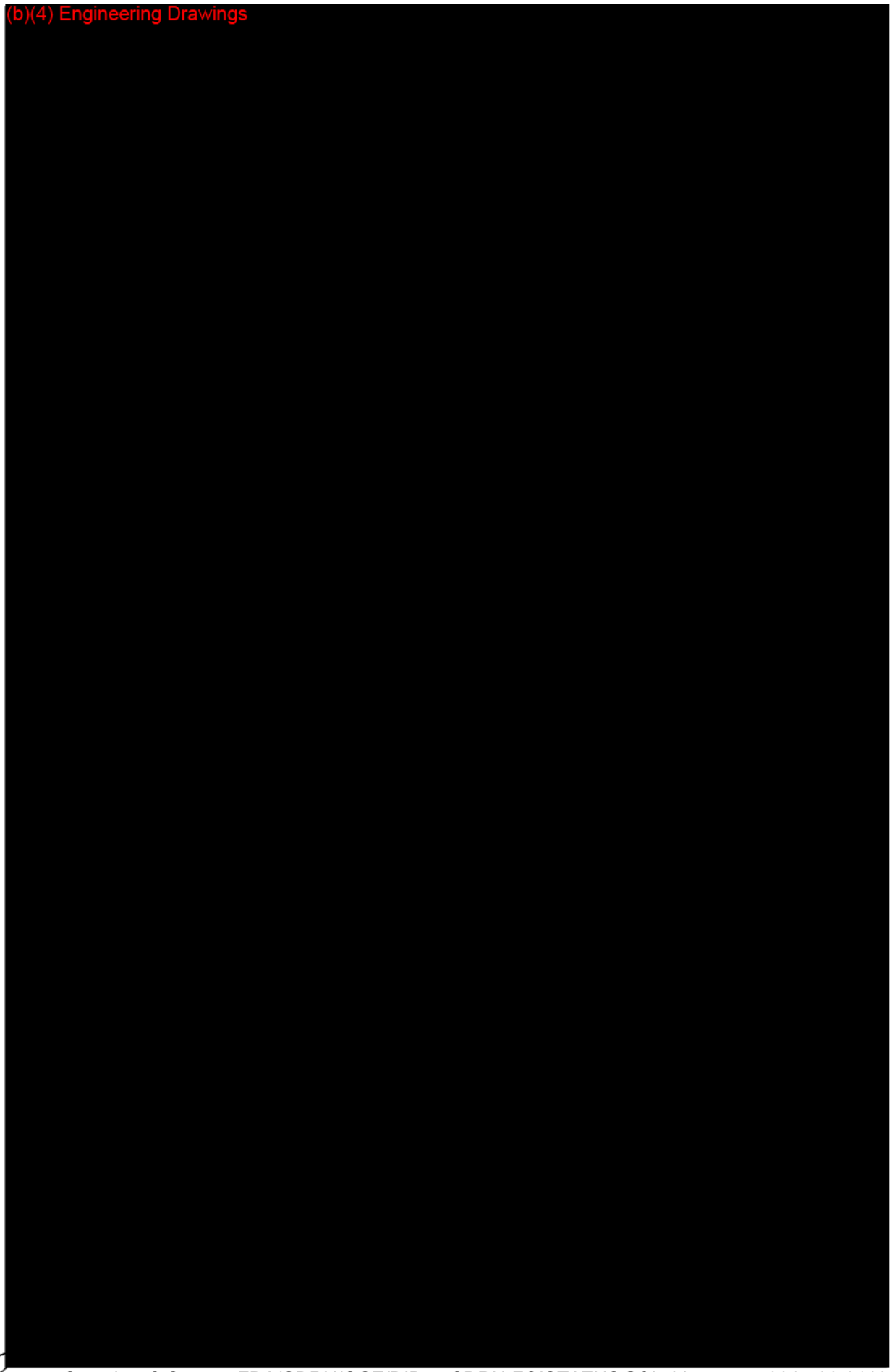
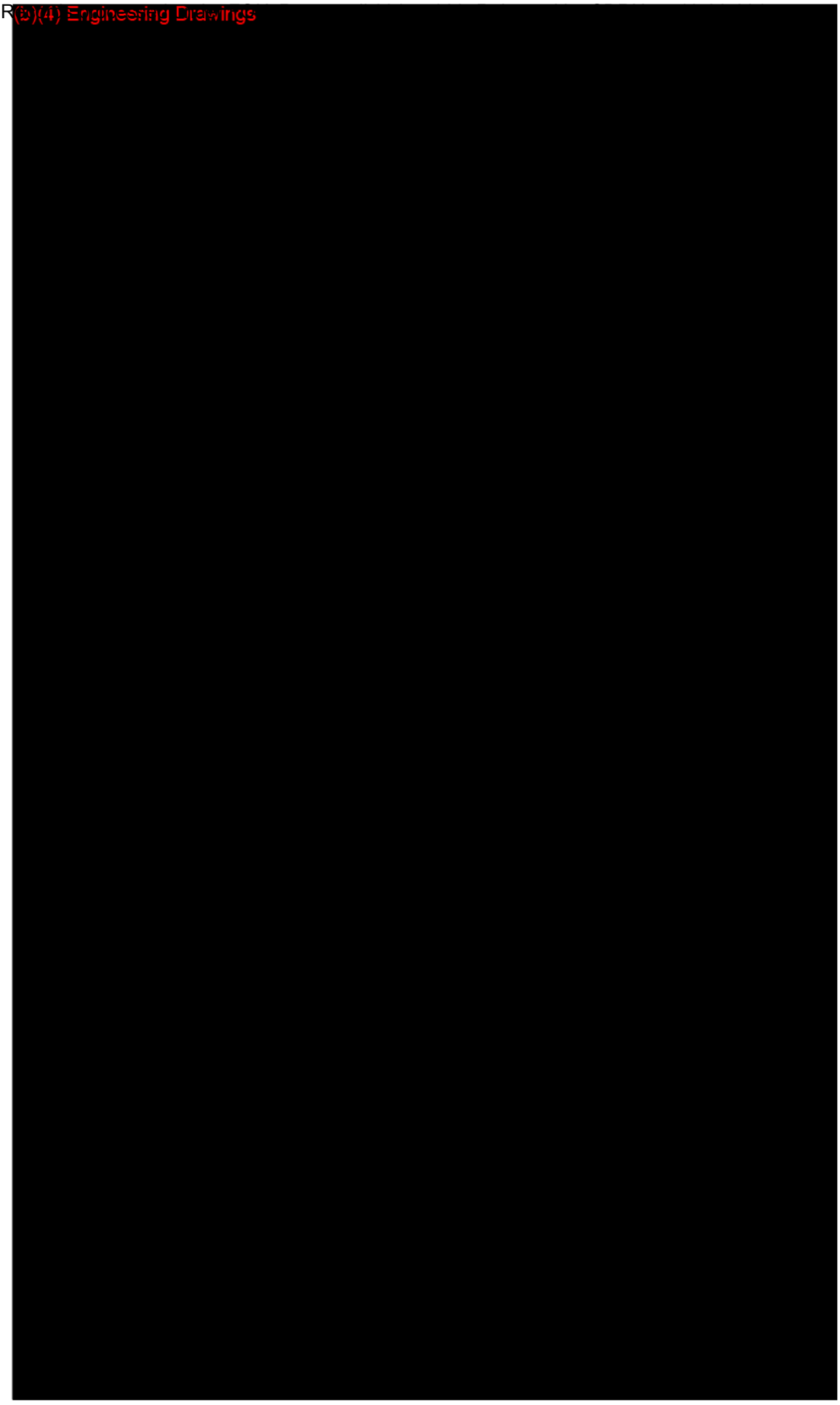
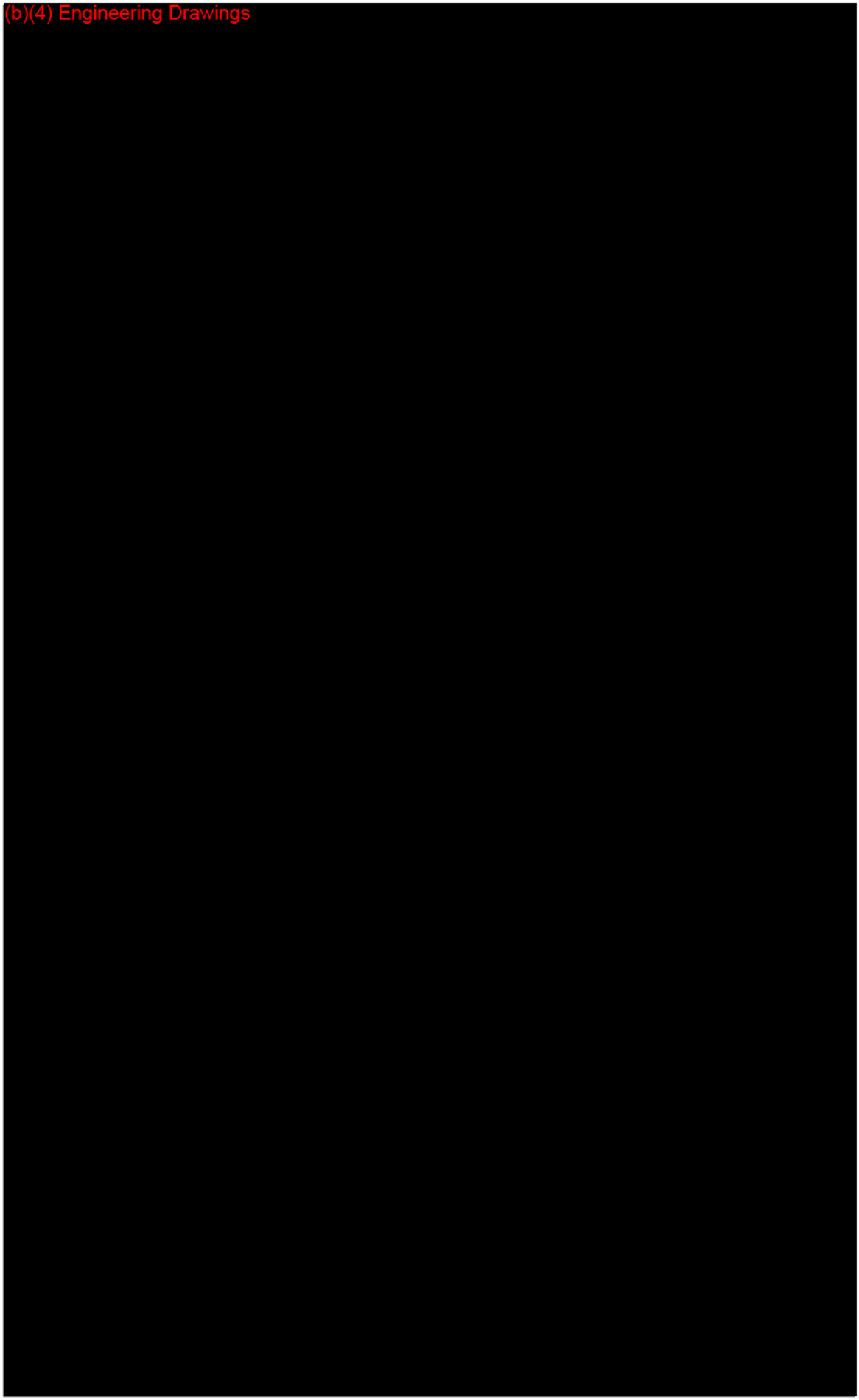
(b)(4) Engineering Drawings

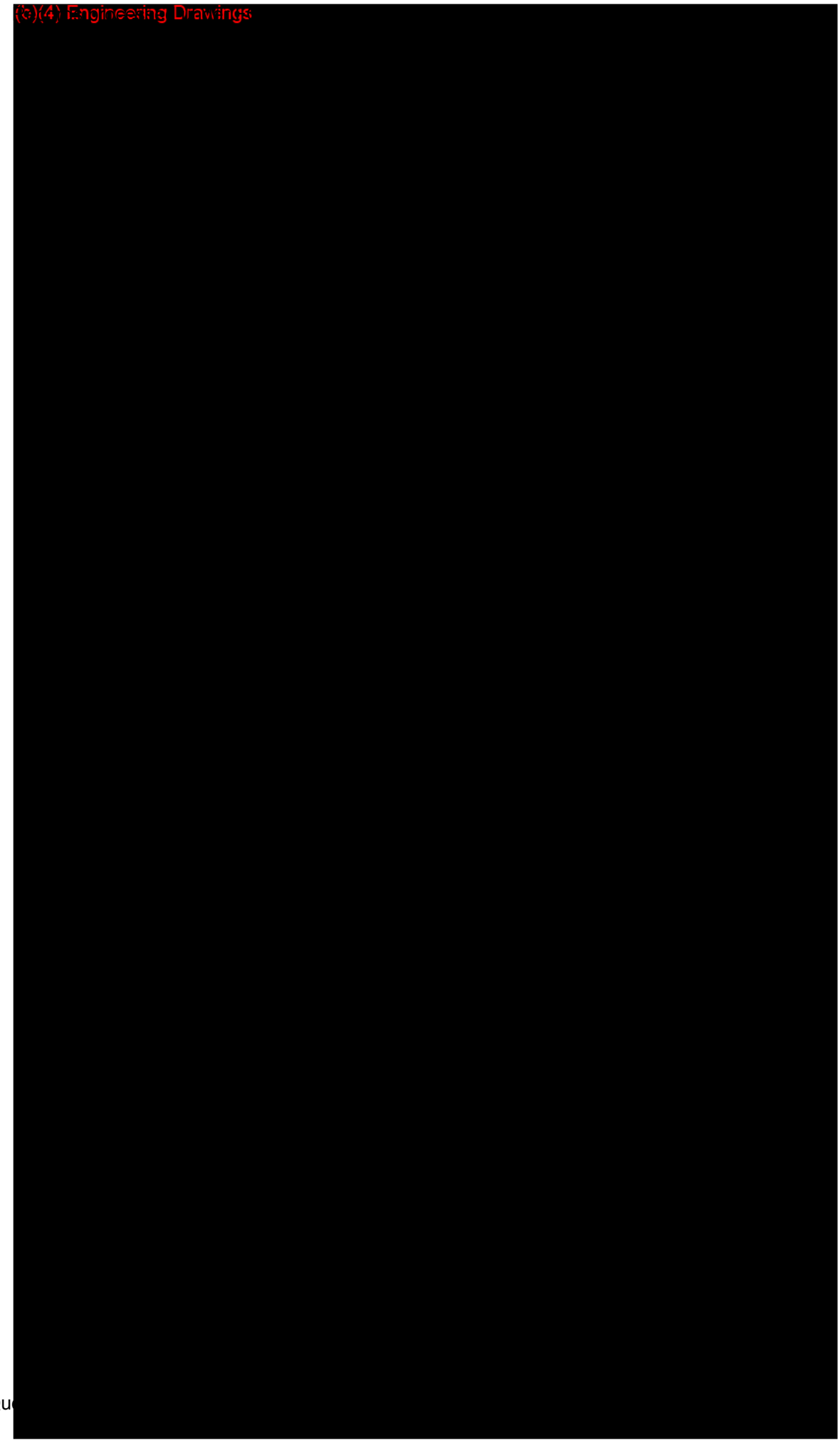




R (b)(4) Engineering Drawings







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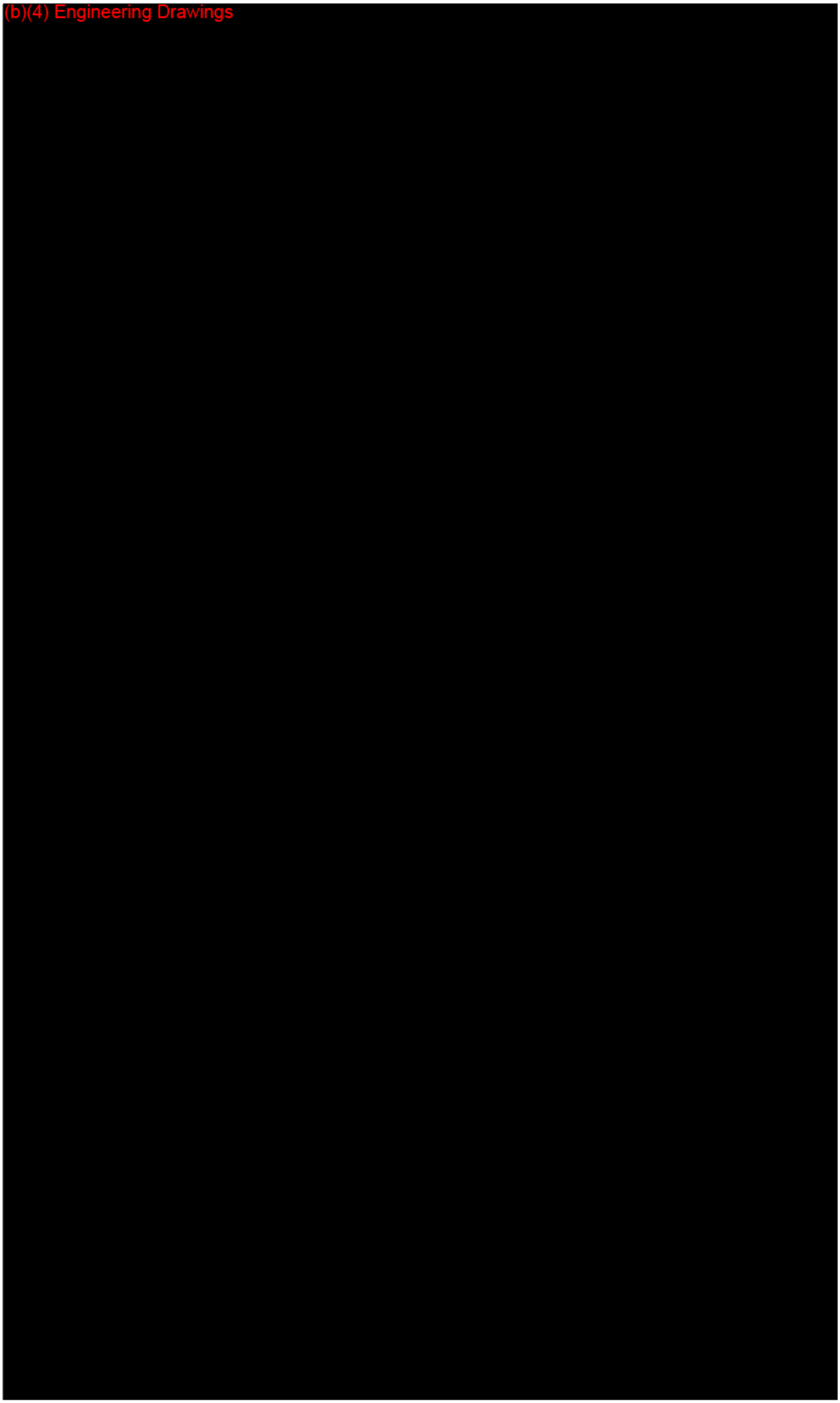

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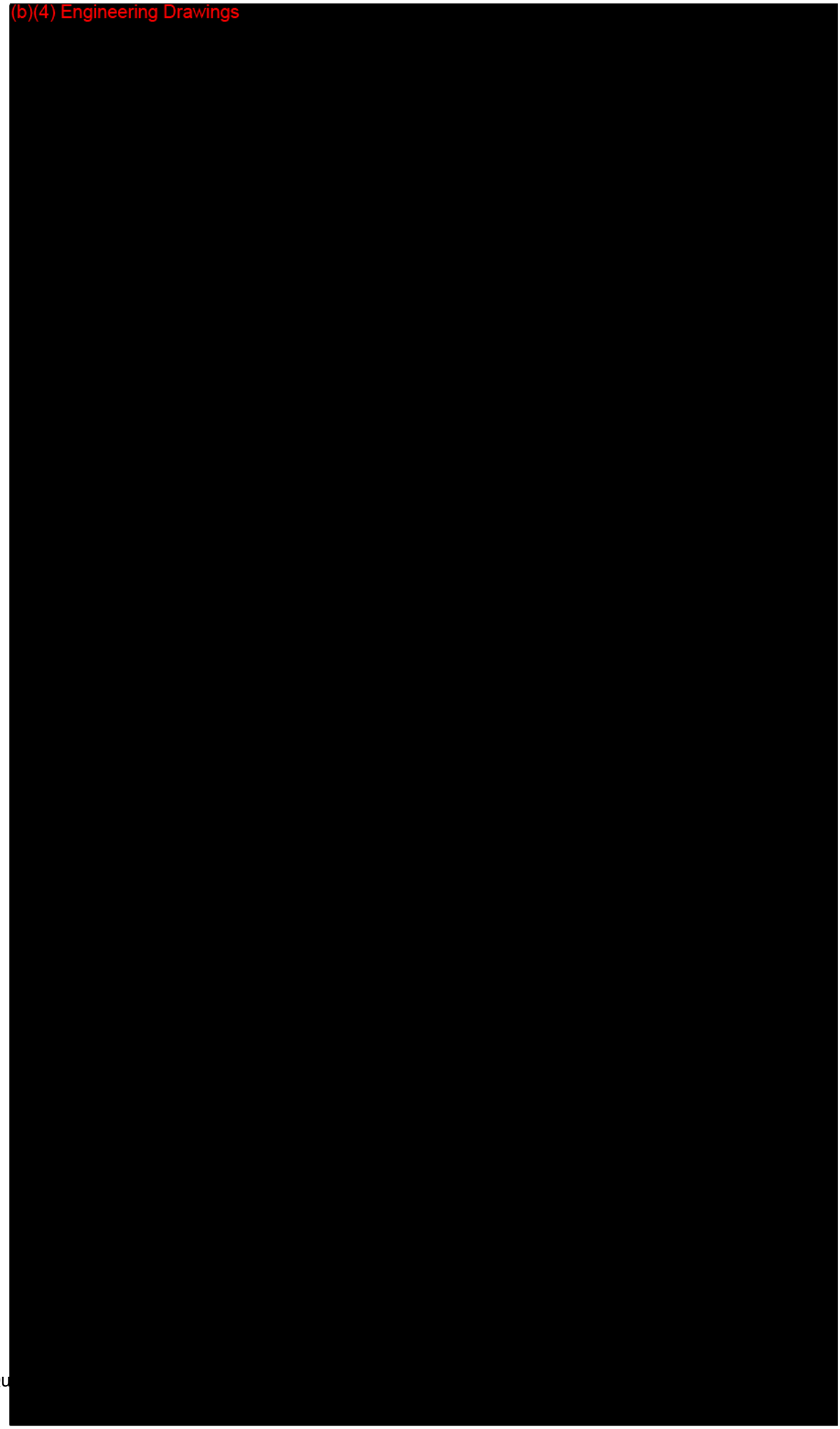
(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

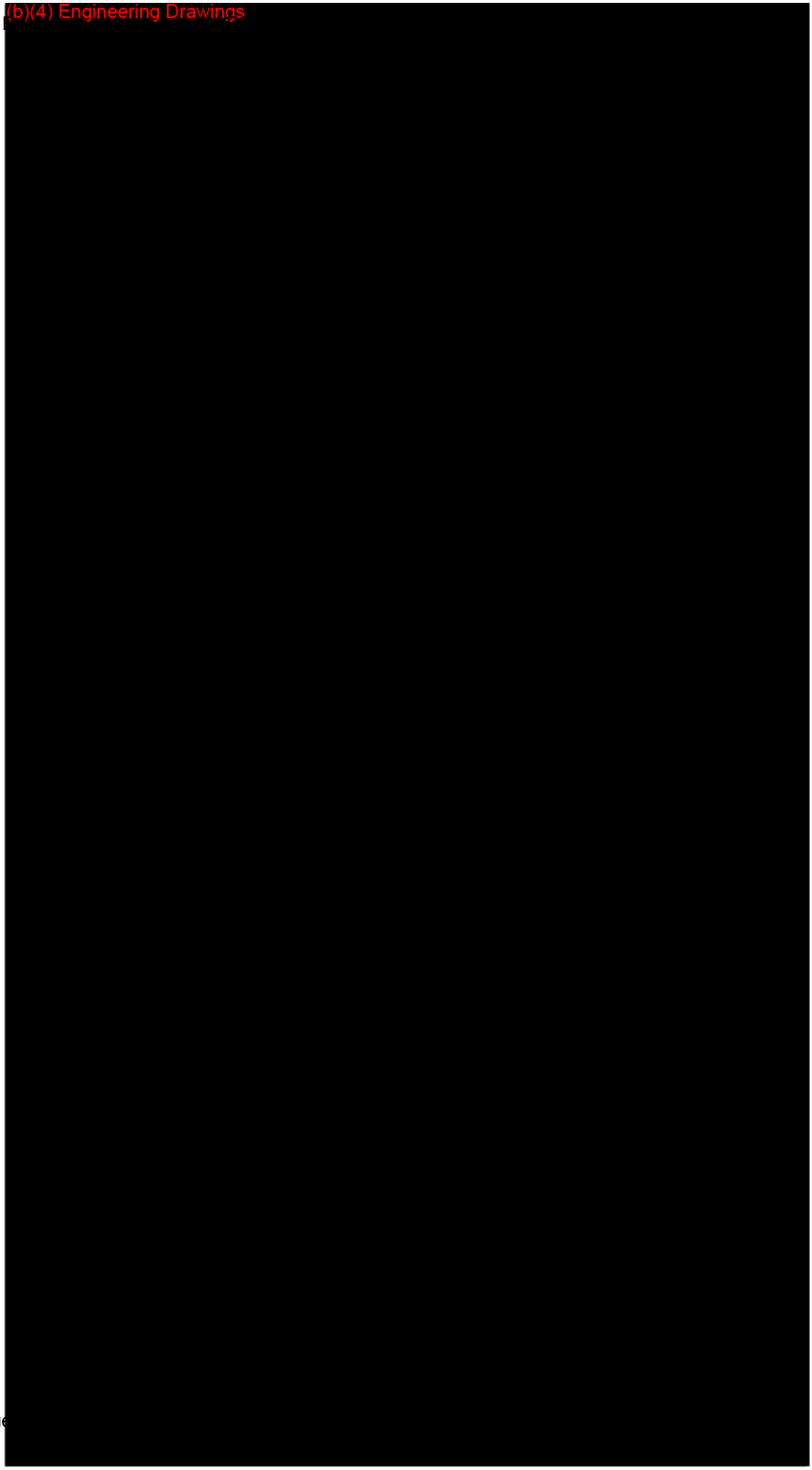

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Exhibit B
Document Control No. K964518

Detailed Comparison Between the Fast-Cath™ Transseptal Catheter Introducer and other Legally Marketed Predicate Devices

The information enclosed under Exhibit B is organized as follows:

Page 1	This page provides a comparison between the Fast-Cath™ Transseptal Catheter Introducer and several other devices on the market.
Pages 2, 3 and 4	These pages provide a photograph of certain predicate devices along with their respective package label.
Page 5	This page provides a photograph of Daig's 8 French, AMAS 1-2 Fast-Cath™ Transseptal Catheter Introducer along with the respective package label.

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Exhibit B
Document Control No. K964518
Page 1

Equivalent Device Comparison

Company	Description	Intended Function *1	FR Size	Sheath Length cm	Dilator Length cm	Material	Tip Marker	Curve
USCI Div. of CR Bard	Transseptal catheter introducer	*2	6	59	67	unknown	no	yes
	Transseptal catheter introducer	*2	7	59	67	unknown	no	yes
	Transseptal catheter introducer	*2	8	59	67	unknown	no	yes
Mansfield Div.of Boston Scientific	Klein transseptal introducer std. curve	*3	8	60	unknown	unknown	yes	yes
	Klein transseptal introducer med. curve	*3	8	60	unknown	unknown	yes	yes
	Klein transseptal introducer short curve	*3	8	60	unknown	unknown	yes	yes
Cook, Inc.	Check-flo Blue introducer, Mullins type	*4	6	63/85	unknown	(b)	no	yes
	Check-flo Blue introducer, Mullins type	*4	7	63/85	unknown	(b)	no	yes
	Check-flo Blue introducer, Mullins type	*4	8	63/85	unknown	(b)	no	yes
	Check-flo Blue introducer, Mullins type	*4	8.5	63/85	unknown	(b))	no	yes
Daig Corporation	Fast-Cath™ Transseptal catheter introducer AMAS 1-2	*5	8	69	74	(b)(4)	yes	yes
	Fast-Cath™ Transseptal catheter introducer AMAS 3-4	*5	8	69	74		yes	yes
	Fast-Cath™ Transseptal catheter introducer AMAS 1	*5	8	62	67		yes	yes
	Fast-Cath™ Transseptal catheter introducer AMAS 2	*5	8	62	67		yes	yes
	Fast-Cath™ Transseptal catheter introducer AMAS 3	*5	8	62	67		yes	yes
	Fast-Cath™ Transseptal catheter introducer AMAS 4	*5	8	62	67		yes	yes
	Fast-Cath™ Transseptal catheter introducer AMAS 1-2	*5	11	59	none		yes	yes
	Fast-Cath™ Transseptal catheter introducer AMAS 3-4	*5	11	63	none		yes	yes

***1 This intended function information was derived from the respective company's catalogs and/or instructions for use manuals.**

*2 Intended for the introduction of various types of cardiovascular catheters into the left side of the heart through the interatrial septum.

*3 Transseptal introducer sheath facilitates access to the left atrium.

*4 Used to introduce balloons, closed and non-tapered end catheters and other devices for intervention.

*5 The intended use for the Daig product is stated as follows: When a procedure involves introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

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KLEIN™

Transseptal Introducer Sheath

Order No.: **5651**

8 Fr

Medium Reach Curve

Contents:

1 – 60cm Radiopaque Introducer Sheath with Hemostasis Valve
1 – Sideport with Stopcock
1 – Radiopaque Vessel Dilator
1 – .038" x 135cm Guidewire with Distal "J" Tip

Lot No. F5177 4R

Expiration Date: 6/97

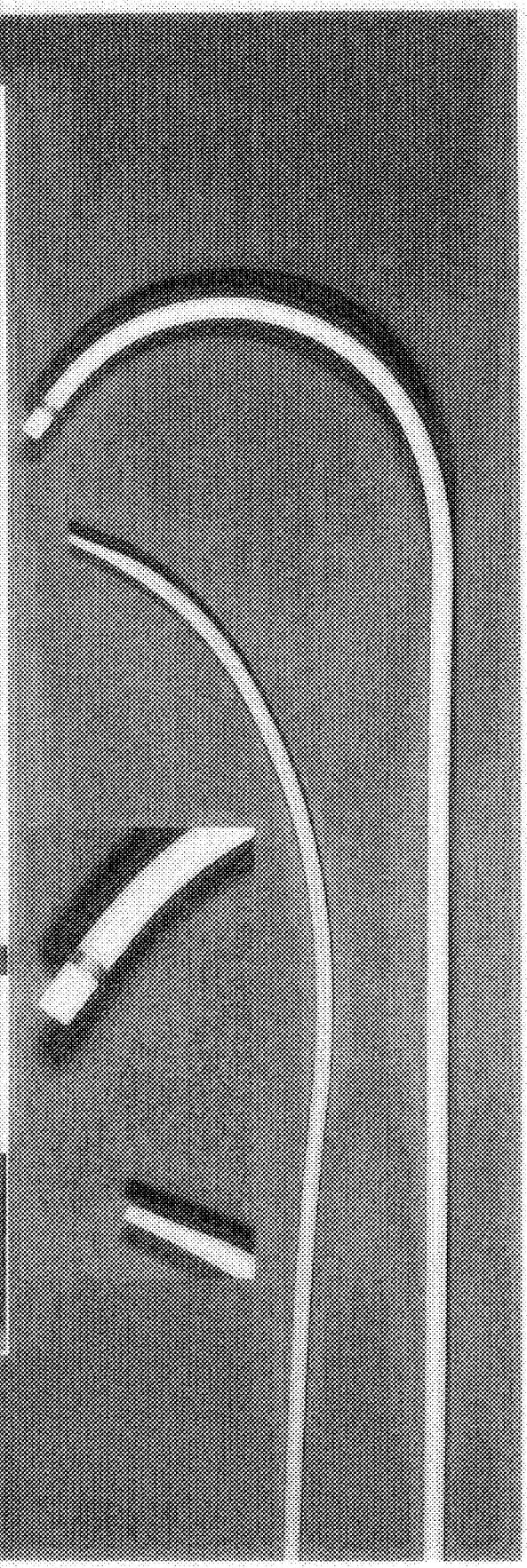
STERILE • SINGLE USE ONLY

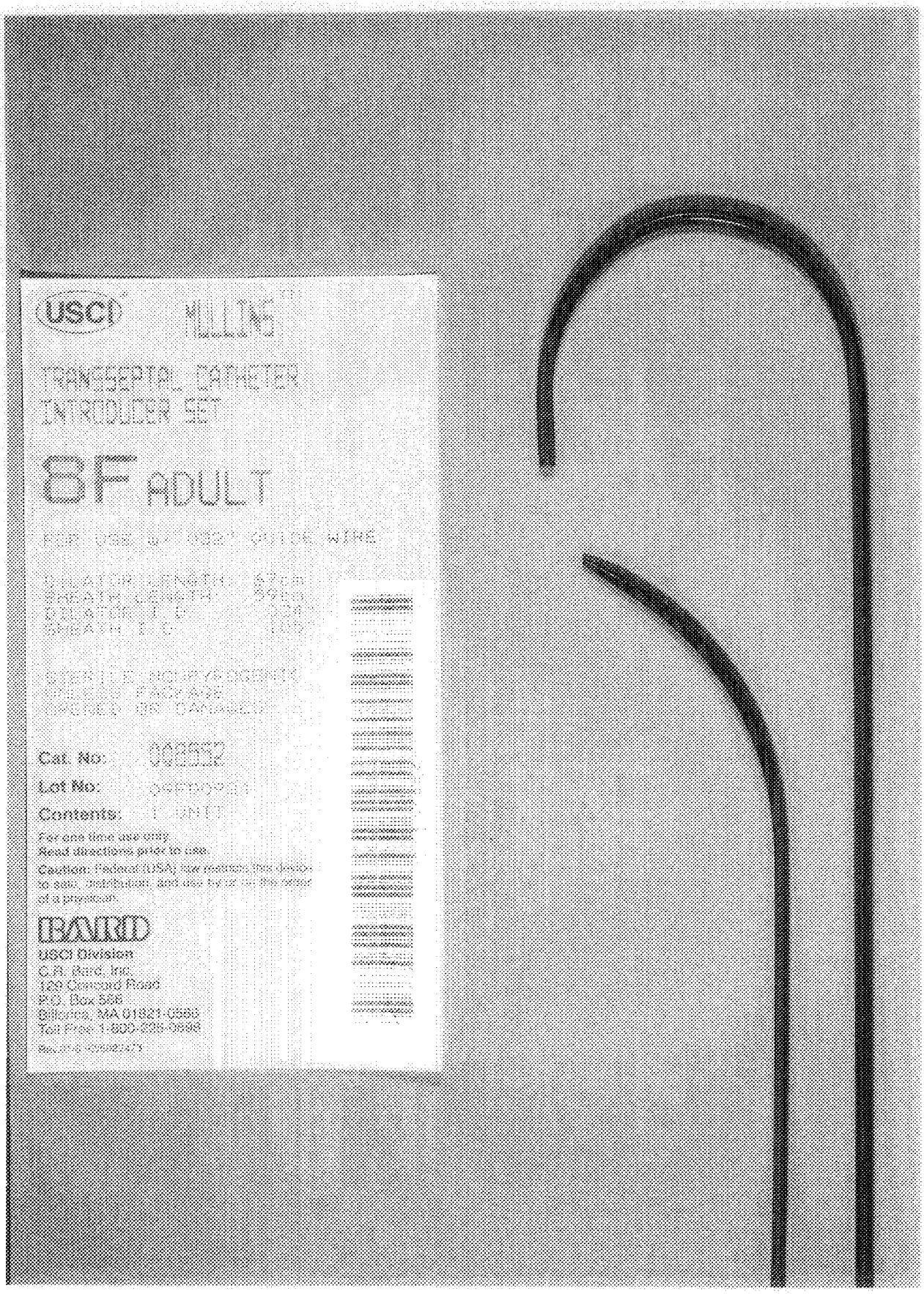
Contents are sterile and non-pyrogenic if package is unopened and undamaged. Caution: Federal Law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician. Read Instructions for Use before using this device. Store at controlled room temperature. Made in U.S.A.

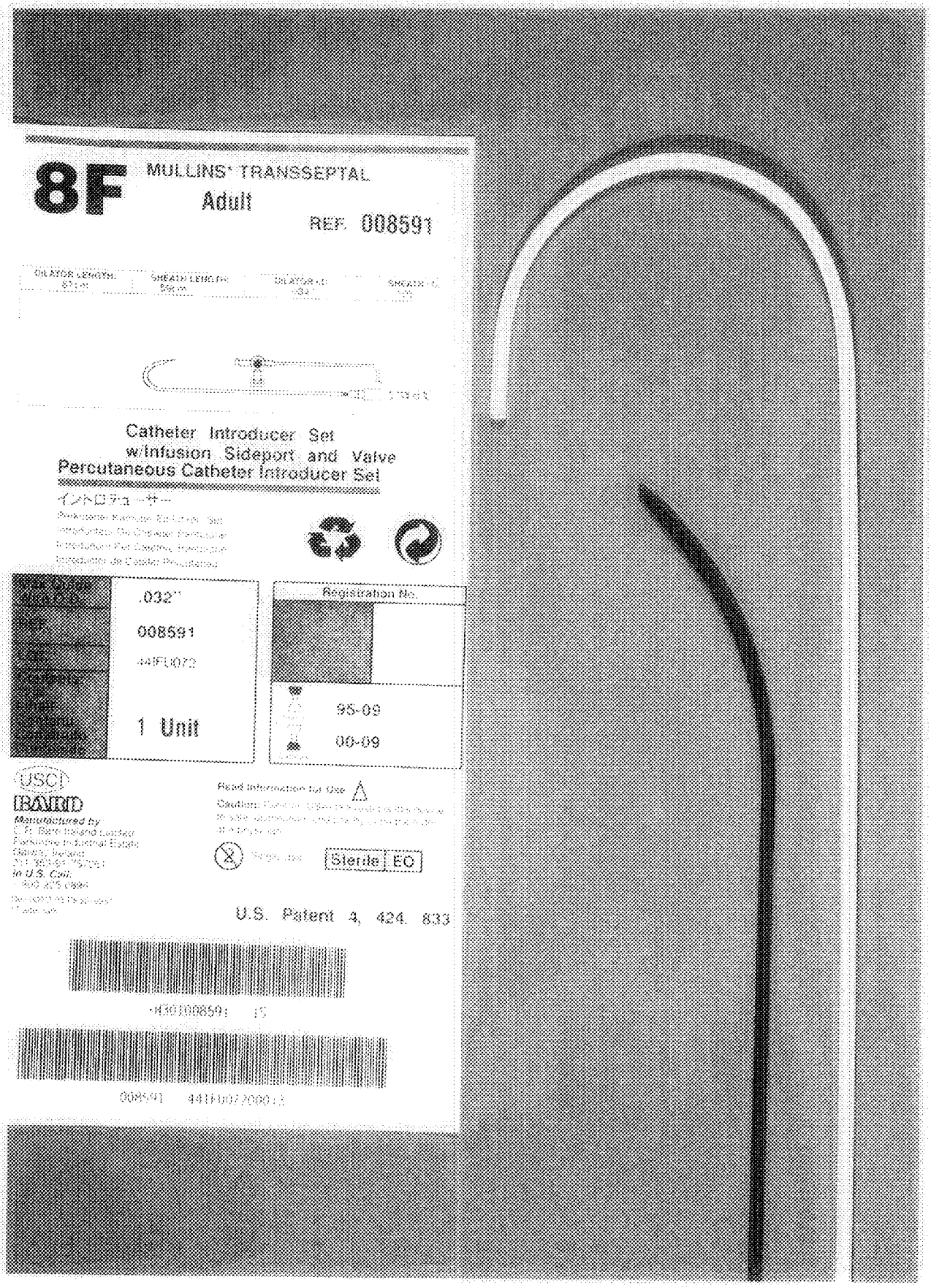
Klein is a trademark of Boston Scientific Corporation.

80351-08 Manufactured For Rev. 11/95

Mansfield EP
Boston Scientific Corporation
480 Pleasant Street, Watertown, MA 02172
(617) 923-1720 / (800) 225-2732







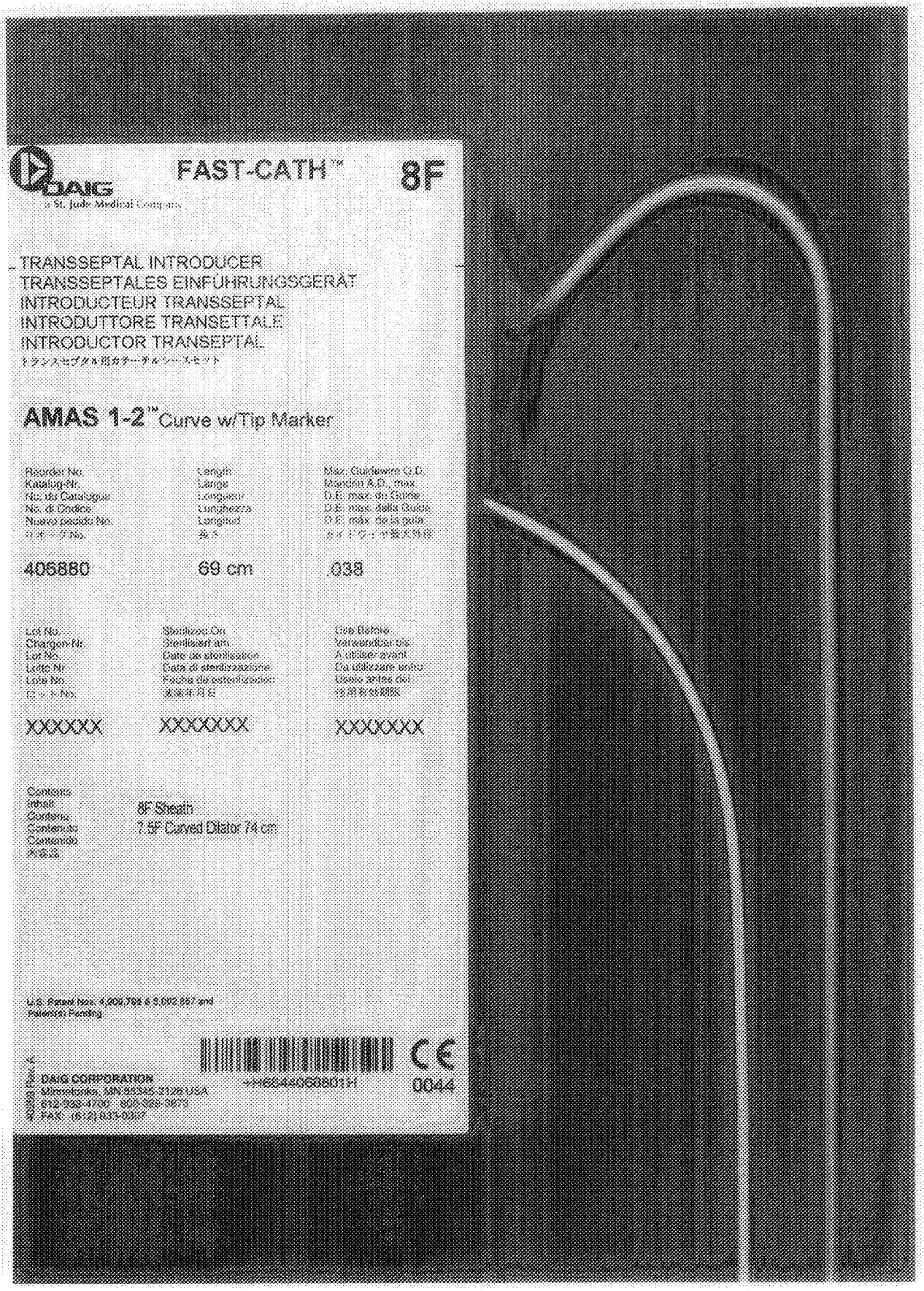


Exhibit C
Document Control No. K964518

Fast-Cath™ Transseptal Catheter Introducer
- Example of Pouch Label -

An example of the revised package label for each Fast-Cath™ Transseptal Catheter Introducer to be marketed is included on the next eight (8) pages.

Pouch Label AMAS2™

DAIG
a St. Jude Medical Company

FAST-CATH™ **8F**

TRANSSEPTAL INTRODUCER
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS2™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダNo.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
406817	62 cm	.032

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロットNo.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
XXXXXX	XXXXXXX	XXXXXXX

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8F Left Heart Sheath
7.5F Curved Dilator, 67 cm
Designed for a Brockenbrough Type Needle

U.S. Patent Nos. 4,909,798 & 5,092,857 and
Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
612-933-4700 800-328-3873
FAX: (612) 933-0307

+H6844068171H

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Pouch Label AMAS1™

DAIG
a St. Jude Medical Company

FAST-CATH™ **8F**

TRANSSEPTAL INTRODUCER
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS1™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダ No.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
406816	62 cm	.032

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロットNo.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
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8F Left Heart Sheath
7.5F Curved Dilator, 67 cm
Designed for a Brockenbrough Type Needle

U.S. Patent Nos. 4,909,798 & 5,092,857 and
Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
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FAX: (612) 933-0307

+H6844068161G

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Pouch Label AMAS3™

DAIG
a St. Jude Medical Company

FAST-CATH™ **8F**

TRANSSEPTAL INTRODUCER
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS3™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダ No.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
406818	62 cm	.032

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロット No.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
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8F Left Heart Sheath
7.5F Curved Dilator, 67 cm
Designed for a Brockenbrough Type Needle

U.S. Patent Nos. 4,909,798 & 5,092,857 and
Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
612-933-4700 800-328-3873
FAX: (612) 933-0307

+H6844068181I

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Pouch Label AMAS4™

DAIG
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FAST-CATH™ **8F**

TRANSSEPTAL INTRODUCER
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS4™ Curve w/Tip Marker

Reorder No. / Katalog-Nr. / No. du Catalogue / No. di Codice / Nuevo pedido No. / リオーダ No.	Length / Länge / Longueur / Lunghezza / Longitud / 長さ	Max. Guidewire O.D. / Mandrin A.D., max. / D.E. max. du Guide / D.E. max. della Guida / D.E. máx. de la guía / ガイドワイヤ最大外径
406819	62 cm	.032

Lot No. / Chargen-Nr. / Lot No. / Lotto Nr. / Lote No. / ロット No.	Sterilized On / Sterilisiert am / Date de stérilisation / Data di sterilizzazione / Fecha de esterilización / 滅菌年月日	Use Before / Verwendbar bis / A utiliser avant / Da utilizzare entro / Uselo antes del / 使用有効期限
XXXXXX	XXXXXXX	XXXXXXX

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8F Left Heart Sheath
7.5F Curved Dilator, 67 cm
Designed for a Brockenbrough Type Needle

U.S. Patent Nos. 4,909,798 & 5,092,857 and
Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
612-933-4700 800-328-3873
FAX: (612) 933-0307

+H6844068191J

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Pouch Label AMAS1-2™

DAIG
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FAST-CATH™ **8F**

TRANSSEPTAL INTRODUCER
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INTRODUCTEUR TRANSSEPTAL
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INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS 1-2™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダ No.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
406880	69 cm	.038

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロットNo.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
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8F Sheath
7.5F Curved Dilator 74 cm

U.S. Patent Nos. 4,909,798 & 5,092,857 and Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
612-933-4700 800-328-3873
FAX: (612) 933-0307

+H6844068801H

CE 0044

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Pouch Label AMAS3-4™

DAIG
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FAST-CATH™ **8F**

– TRANSSEPTAL INTRODUCER –
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS 3-4™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダ No.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
406881	69 cm	.038

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロットNo.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
XXXXXX	XXXXXXX	XXXXXXX

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8F Sheath
7.5F Curved Dilator 74 cm

U.S. Patent Nos. 4,909,798 & 5,092,857 and Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
612-933-4700 800-328-3873
FAX: (612) 933-0307

+H68440688111

CE 0044

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Pouch Label AMAS1-2™

DAIG
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FAST-CATH™ 11F

– TRANSSEPTAL INTRODUCER –
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS 1-2™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダ No.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
406882	59 cm	--

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロット No.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
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11F Sheath

U.S. Patent Nos. 4,909,798 & 5,092,857 and
Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
612-933-4700 800-328-3873
FAX: (612) 933-0307

+H6844068821J

CE 0044

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Pouch Label AMAS3-4™

DAIG a St. Jude Medical Company

FAST-CATH™ 11F

– TRANSSEPTAL INTRODUCER –
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS 3-4™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダ No.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
406883	63 cm	--

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロットNo.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
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11F Sheath

U.S. Patent Nos. 4,909,798 & 5,092,857 and Patent(s) Pending

40959 Rev. A

DAIG CORPORATION
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+H6844068831K

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Exhibit D
Document Control No. K964518

Labeling:
Required Caution Prescription Statement

An example of the box labeling for Daig's Fast-Cath™ Transseptal Catheter Introducer (page 1) and an example of the text which appears on the pouch label for Daig's Fast-Cath™ Transseptal Catheter Introducer (page 2) both contain the following statement:

"CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO USE BY OR ON THE ORDER OF A PHYSICIAN."

Single use device. Do not resterilize.
Einmalgebrauchsartikel. Nicht resterilisieren.
Matériel a usage unique. Ne pas restériliser.
Dispositivo monouso. Non risterilizzare.
Dispositivo para un solo uso. No lo vuelva a esterilizar.
1回限りの使用．滅菌・再使用できません．

See instructions for use in master carton.
Siehe Gebrauchsanweisung im Außenkarton.
Se reporter au mode d'emploi dans le carton d'emballage.
Vedere istruzioni per l'uso nel pacco principale.
Vea las instrucciones para el uso en la caja de embarque.
使用方法は、中の取扱説明書を参照してください．

Store in a cool, dark, dry place.
Kühl, dunkel und trocken aufbewahren.
A conserver dans un endroit frais et sec, à l'abri de la lumière.
Conservare in luogo fresco e asciutto e al riparo della luce.
Almacenar en un lugar fresco, oscuro y seco.
乾燥した冷暗所に保管して下さい。

Contents are sterile if package is unopened and undamaged.
Inhalt ist steril, solange die Packung ungeöffnet und unbeschädigt ist.
Le contenu est stérile si l'emballage n'est pas ouvert et endommagé.
Il contenuto è sterile se l'involucro è chiuso ermeticamente e non è danneggiato.
Contenido estéril si el paquete está cerrado y sin daños.
パッケージが未開封で、破損、汚染等がなければ、内容物は殺菌済です．

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

STERILE | EO

PRINTED WITH SOY INK™
and other environmentally friendly inks.

ENVIRONMENTAL INFORMATION
THIS BOX AND ITS CONTENTS ARE RECYCLABLE

DAIG and the stylized D – Reg. U.S. Pat. & Tm. Off.

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Single use device. Do not resterilize.
Einmalgebrauchsartikel. Nicht resterilisieren.
Matériel a usage unique. Ne pas restériliser.
Dispositivo monouso. Non risterilizzare.
Dispositivo para un solo uso. No lo vuelva a esterilizar.
1回限りの使用。滅菌・再使用できません。

Contents are sterile if package is unopened and undamaged.
Inhalt ist steril, solange die Packung ungeöffnet und unbeschädigt ist.
Le contenu est stérile si l'emballage n'est pas ouvert et endommagé.
Il contenuto è sterile se l'involucro è chiuso ermeticamente e non è danneggiato.
Contenido estéril si el paquete está cerrado y sin daños.
パッケージが未開封で、破損、汚染等がなければ、内容物は殺菌済です。

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

Store in a cool, dark, dry place.
Kühl, dunkel und trocken aufbewahren.
A conserver dans un endroit frais et sec, à l'abri de la lumière.
Conservare in luogo fresco e asciutto e al riparo della luce.
Almacenar en un lugar fresco, oscuro y seco.
乾燥した冷暗所に保管して下さい。

See instructions for use in master carton.
Siehe Gebrauchsanweisung im Außenkarton.
Se reporter au mode d'emploi dans le carton d'emballage.
Vedere istruzioni per l'uso nel pacco principale.
Vea las instrucciones para el uso en la caja de embarque.
使用方法は、中の取扱説明書を参照してください。

STERILE	EO

13107 Rev. 01/96

Exhibit E
Document Control No. K964518

Fast-Cath™ Transseptal Catheter Introducer
- Instructions for Use -

A revised copy of the Instructions for Use are included as Exhibit E.

Daig Response to FDA Item 3c.

(b)(4)

[redacted]

Daig Response to FDA Item 3d.

(b)(4)

[redacted]

DAIG
a St. Jude Medical Company

INSTRUCTIONS FOR USE

FAST-CATH™

TRANSSEPTAL CATHETER INTRODUCER WITH HEMOSTASIS VALVE

SEE PRODUCT CATALOG FOR PRODUCT REORDER NUMBERS AND SPECIFICATIONS.

Read Instructions for Use prior to use of this device.

SEE INDIVIDUAL STERILE PACKAGE LABEL FOR CONTENTS.

SINGLE-USE DISPOSABLE MEDICAL DEVICE.
CONTENTS ARE STERILE IF PACKAGE IS UNOPENED AND UNDAMAGED.
DO NOT RESTERILIZE.

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INDICATIONS

When introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

CONTRAINDICATIONS

- Previous intra-atrial septal patch.
- Previous systemic embolization from the left side of the heart.
- Known or suspected left atrial myxoma.
- Myocardial Infarctions within the last two weeks.
- Unstable angina.
- Recent Cerebral Vascular Accident (CVA).
- Patients who do not tolerate anticoagulation therapy.
- Patients with an active infection.

PRECAUTIONS

- Inspect all components before use.
- Federal (U.S.A.) law restricts this device to use by or on the order of a physician.
- The French size specified represents the inner diameter of the introducer sheath.
- Do not attempt to insert a catheter having a distal tip or body size larger than the introducer size indicated.
- The Daig hemostasis introducer is designed to interlock only with Daig dilators. Misuse may result in serious complications.
- Do not attempt to use a guidewire over maximum diameter specified on package label.
- Carefully reading the Instructions before use of this device will help to reduce the potential dangers associated with the transseptal technique such as air emboli and/or perforation of the aorta and left atrium.
- Prior to inserting the device into the patient, pre-assemble the sheath and dilator.
- During insertion, use caution not to create excessive bends in this device.
- Frequently aspirate and saline flush the sheath to minimize the potential for emboli.
- Do not remove dilator or catheter rapidly. Damage to the backbleed valve may occur.
- If resistance is met when advancing or withdrawing guidewire or introducer, determine cause and correct before continuing with this procedure.
- Indwelling percutaneous introducer sheaths should always be supported with a catheter.
- Aspirate only from the sideport.
- Inject or saline flush only from the sideport.

- Certain conditions may require special consideration when using this product. These may be, but are not limited to: Enlarged Aortic Root, Small Left Atrium, Marked Right Atrial Enlargement, Marked Distortion of the Thorax Configuration (i.e. Kyphosis or Scoliosis).
- **STORE IN A COOL, DARK, DRY PLACE.**

WARNINGS

- Do not alter this device in any way.
- **Only those physicians who are specially trained in transseptal procedures and Daig catheter delivery systems should use this device.**
- Do not reuse this device. Thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device.
- Maintain continuous pressure monitoring throughout the procedure.
- Maintain anterior-posterior and lateral fluoroscopy throughout the procedure.
- Always observe acceptable pressure tracings prior to advancing the dilator or any other component.
- Do not create a vacuum in the sheath. Remove components and make catheter exchanges slowly.
- From the sideport only—aspirate all air prior to infusion.
- Provide a continuous drip under pressure when the introducer remains in the vessel.
- Fibrin may accumulate in or on the sheath tip during the procedure. Aspirate when removing dilator or catheter.
- Reinsert the dilator fully into the introducer sheath to aid in straightening the tip portion. Then remove the dilator and introducer sheath as a unit.

DESCRIPTION

The Daig Transseptal Catheter Introducer Set consists of a radiopaque sheath and a dilator each with specially curved distal portions to accommodate positioning in the cardiac anatomy. The introducer sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring.

SUGGESTED PROCEDURE

- To determine size and location of left atrium and atrial septum, it may be helpful to perform right side angiography.
- Obtain a Daig Transseptal Catheter Introducer Set designed for a Brockenbrough type curved puncture needle.
- Use only a Brockenbrough type curved puncture needle.

  CAUTION: Observe the precautions specified in the instructions provided with the Daig Transseptal Catheter Introducer.
- Thoroughly flush sheath thru the sideport, filling sheath column with saline.
- Thoroughly flush dilator, filling dilator column with saline.
- Assemble the dilator and sheath and "snap" the dilator into the sheath hub.

S/

- Once dilator is fully positioned in sheath, introduce additional saline through the sideport to ensure all air is removed from the area between dilator and sheath.
- Position an .032" diameter guidewire well into the Superior Vena Cava (SVC).
- Introduce the dilator/sheath assembly as a unit over the guidewire.
- Advance the dilator/sheath assembly into the Superior Vena Cava (SVC) just above the right atrium. Verify with fluoroscopy.
- Separate the snap-lock hubs of the dilator and sheath and slowly advance the sheath 1 cm as shown by the proximal markings on the dilator body.
- Remove the guidewire.
- Allow blood to aspirate in order to clear dilator of any possible air. Flush as required.
- Thoroughly flush long, curved septal puncture needle.
- Pass the needle into the dilator and advance the curved distal portion past the sheath hub. The separation of dilator and introducer hubs better accommodates the introduction of the curved septal puncture needle.
- Allow the needle to move freely as the curved distal portion passes through the dilator and introducer hubs.
- Reattach the dilator hub and introducer hub.
- Slowly advance the needle into the dilator so that the needle tip is within the tip of the dilator.

  NOTE: Make sure the needle is free to twist and/or rotate without resistance as it is advanced to this position.

- Connect the needle hub to pressure monitoring equipment. Make sure that good atrial pressure is observed prior to proceeding.

  NOTE: The pressure monitoring capability is only intended to assist in the location of the catheter within the heart.

- Slowly withdraw the needle, sheath and dilator as an assembly from the Superior Vena Cava, allowing the assembly to curve toward and position themselves in the right atrium and against the atrial septum in the region of the fossa ovalis. Use gradual rotation of the needle posteriorly and toward the left scapula during this withdrawal.

  NOTE: Continual pressure monitoring and repeated anterior-posterior and lateral fluoroscopic monitoring during any positioning cannot be overemphasized.

- Proceed with the transseptal puncture and advance the needle.

  You will experience a slight buildup of resistance followed by a sudden release of back pressure as the needle passes through the septum and enters the left atrium.

- Confirm with pressure monitoring.

  CAUTION: Immediately following penetration of the interatrial septum, observe acceptable left atrial pressure on the pressure monitoring equipment.

  NOTE: Remove the pressure monitoring line and slowly inject a small volume of contrast medium through the needle to identify the area of penetration in the septum or wall of the left atrium.

- Advance the dilator with the needle through the septum by using firm but not undo pressure. Continue to observe acceptable atrial pressure. You should experience a slight release of back pressure as the dilator penetrates the septum.

- Using fluoroscopy, withdraw the needle to a point just inside the dilator tip. Position the dilator/needle freely in the left atrium.
- Advance the sheath over the dilator into the left atrium.

  NOTE: Continue to observe that the needle is located within the dilator tip.

  NOTE: Rotate the sheath back and forth while applying slight forward pressure, a release of which is felt as the sheath penetrates the septum.
- Remove the pressure monitoring line from the needle. Turn stopcock to "off" position.
- Withdraw the needle slowly from the dilator.
- Remove the dilator slowly from the sheath.

  CAUTION: Always withdraw components slowly to minimize the vacuum created during withdrawal.
- Reattach the monitoring line to the sheath sideport.
- Aspirate the sheath through the sideport for sampling purposes.

  CAUTION: The sheath tip may be resting against the atrium or pulmonary vein as evidenced by a lack of free-flowing blood. Rotate the sheath or withdraw the sheath 1/2 to 1 cm and reestablish blood flow.
- Note the distance of the sheath hub from the puncture site.
- Follow manufacturer's recommendations for the catheter or device being introduced via the hemostasis introducer.

  CAUTION: Care should be taken to ensure the distal tip portion of the sheath remains across the septum and well into the left atrium.
- **Reinsert the dilator fully into the introducer sheath to aid in straightening the tip portion. Then remove the dilator and introducer sheath as a unit.**

  NOTE: If the larger lumen Daig Transseptal Catheter Introducer is being used in combination with a longer and smaller lumen Daig Transseptal Catheter Introducer as an "inner/outer" set, the following applies:
- Advance an .032" diameter guidewire through the dilator, across the septum and well into the left atrium. Verify with fluoroscopy.

  NOTE: Repeated anterior-posterior and lateral fluoroscopic monitoring during any positioning cannot be overemphasized.
- Withdraw the dilator/sheath assembly as a unit leaving the guidewire in position in the left atrium.

  CAUTION: Always withdraw components slowly to minimize the vacuum created during withdrawal.
- Assemble the dilator into the inner sheath. Assemble the dilator/inner sheath assembly into the outer sheath.
- Introduce the two (2) piece sheath and dilator assembly as a unit over the guidewire.
- Slowly aspirate all air from each sheath using a syringe attached to one of the ports of each of the three-way stopcocks.

  NOTE: Provide a pressurized saline flush through the sideport.
- Advance the two (2) piece sheath and dilator assembly over the guidewire until the dilator is positioned freely within the left atrium. Verify with fluoroscopy.
- While the dilator remains stationary, advance the inner/outer sheath assembly over the dilator until the inner sheath is positioned freely in the left atrium. Verify with fluoroscopy.

- While the inner sheath/dilator assembly remains stationary, advance the outer sheath over the inner sheath until transseptal crossing is achieved. Verify with fluoroscopy.
- Slowly remove dilator and guidewire from inner sheath.

  CAUTION: Always withdraw components slowly to minimize the vacuum created during withdrawal.
- Reattach the monitoring line to the inner sheath sideport.
- Aspirate the inner sheath through the sideport for sampling purposes.

  CAUTION: If the inner sheath tip has been withdrawn into the outer sheath, the outer sheath tip may be resting against the atrium or pulmonary vein as evidenced by a lack of free-flowing blood. Rotate the sheath assembly or withdraw the assembly 1/2 to 1 cm and reestablish blood flow.
- Note the distance of the outer sheath hub from the puncture site.
- Follow manufacturer's recommendations for the catheter or device being introduced via the hemostasis introducer.

  CAUTION: Care should be taken to ensure the distal tip portion of the sheath assembly remains across the septum and well into the left atrium.
- **Reinsert the dilator fully into the introducer sheath to aid in straightening the tip portion. Then remove the dilator and introducer sheath as a unit.**

LIMITED WARRANTY AND DISCLAIMER

Daig Corporation ("Daig") hereby warrants that if any Daig product fails to perform within normal tolerances for a patient due to a defect in materials or workmanship, Daig will provide, at no charge, a replacement Daig product for the patient's use. This limited warranty applies only if each of the following conditions are met.

1. The product was packaged and labeled by Daig.

2. The failed product must be returned to Daig and becomes the property of Daig.

3. The product has not been mishandled, reprocessed or altered in any way.

4. The product was used before the "USE BEFORE" date marked on the packaging of the product.

No representation or warranty is made that a Daig product will not fail. Daig disclaims responsibility for any medical complications, including death, resulting from the use of its products. Except as expressly provided by this limited warranty, DAIG IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUNCTION OF ITS PRODUCTS, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE. Some states do not allow the exclusion or limitation of incidental or consequential damages however. so the above limitation or exclusion may not apply to you.

Except as expressly provided by the limited warranty, DAIG MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

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DAIG CORPORATION
14901 DeVeau Place
Minnetonka, MN 55345-2126 USA

TEL: (800) 328-3873
In MN, call: (612) 933-4700
FAX: (612) 933-0307

ST. JUDE MEDICAL EUROPE, INC.
Arianelaan 5
1200 Brussels
Belgium

TEL: 32 2 774 68 11
FAX: 32 2 772 83 84

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2/97

STERILE EO

CE 0044

Exhibit F
Document Control No. K964518

Fast-Cath™ Transseptal Catheter Introducer (b)(4) Test Results -

The independent laboratory tests demonstrating compliance with the (b)(4) (b)(4) similar devices using the same package configuration are included in this exhibit.

(b)(4) Third Party Testing

(b)(4) Third Party Testing

510(k) Number (if known): K964518

Device Name: Fast-Cath™ Transseptal Catheter Introducer

Indications for Use:

Daig Fast-Cath™ Transseptal Catheter Introducers are designed for use when a procedure involves introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DAIG
A St. Jude Medical Company

Amendment No. 1
510(k)
Document Control No. K964518

Fast-Cath™
Transseptal Catheter Introducer

Establishment Registration No. 2182269

Daig Corporation
14901 DeVeau Place
Minnetonka, MN 55345-2126
Tel. (612) 933-4700

February 13, 1997

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

JAN 22 1997

Mr. John C. Heinmiller
Official Correspondent
Daig Corporation
14901 DeVeau Place
Minnetonka, Minnesota 55345-2126

Re: K964518
Fast-Cath™ Transseptal Catheter Introducer
Dated: October 24, 1996
Received: October 25, 1996

Dear Mr. Heinmiller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4)

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have questions concerning the contents of this letter, please contact Kimberly Bowie Peters at (301) 443-8243. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

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

Enclosure

Mr. John C. Heinmiller
Official Correspondent
Daig Corporation
14901 DeVeau Place
Minnetonka, Minnesota 55345-2126

Re: K964518
Fast-Cath™ Transseptal Catheter Introducer
Dated: October 24, 1996
Received: October 25, 1996

Dear Mr. Heinmiller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4) Deficiencies

[redacted]

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(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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Sincerely yours,

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

Enclosure

Prepared by:KPETERS:swf:1/13/97
final;swf:1/22/97
cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-450	Peters	1/20/97						
HFZ-450	J Gongleton	1/22/97						
450		1/22/97						

U.S. GPO 1986-169-089

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Kimberly Bowie Peters — January 13, 1997

Subject: 510(k) Number K964518

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Is substantially equivalent to marketed devices.
- ☐ Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☑ Requires more data. See attached review
- ☐ Accepted for review _____ (date)
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☐NO
Is this device subject to the Tracking Regulation?	☐YES	☐NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☐NO
Is this a prescription device?	☐YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☐NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☑ Enclosed (Section 3)
(required for originals received 3-14-95 and after)

☐A 510(k) summary OR ☑A 510(k) statement (Section 4)

☐ The required certification and summary for class III devices NA

☐ The indication for use form (required for originals received 1-1-96 and after) (

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☑ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: —

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

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised: 7-1-96

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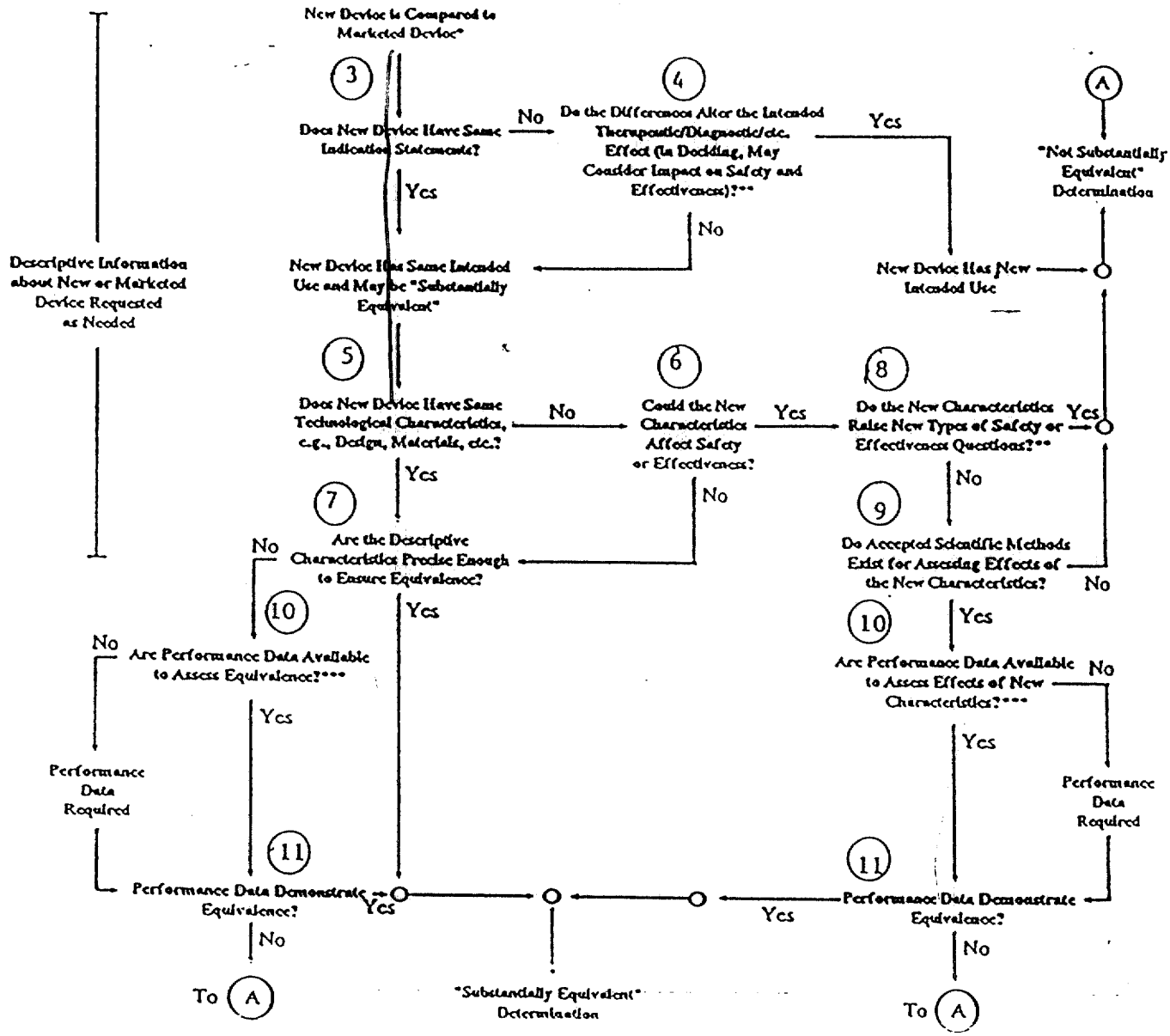
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Avenue
Rockville, MD 20850

MEMORANDUM TO THE RECORD
Premarket Notification [510(k)] Review
K964518

DATE: January 7, 1997
FROM: Kimberly Bowie Peters

OFFICE: HFZ-450
DIVISION: DCRND/ICDG

COMPANY NAME: Daig Corporation
DEVICE NAME: Fast-Cath Transseptal Catheter Introducer

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. **REASON FOR SUBMISSION:**
This premarket notification submission addresses the addition of curve styles to the currently marketed line of Fast-Cath Transseptal Catheter Introducer (K911883).

2. **INTENDED USE:**
The Fast-Cath Transseptal Catheter Introducer is intended for use when introducing various cardiovascular catheters into the left side of the heart through the interartial septum.

The currently marketed Fast -Cath Transseptal Catheter Introducer cleared in K911883 features the same indications for use statement.

3. **DEVICE DESCRIPTION:**

A. **Life-supporting or life sustaining:** No
B. **Implant (short-term or long term):** No
C. **Is the device sterile?** Yes
If yes, is sterility information provided? Yes (section 10)

The sterilization information does not clearly identify the sterilization method used, the validation method, the sterility assurance level that will be met, and the residual levels of [redacted] (b)(4) that will be met. The information does indicate that [redacted] testing will be performed per USP XXII on each sterilized lot.

Packaging of the Fast-Cath Transseptal Catheter Introducer will be the same as that used for the currently marketed Daig devices. The sterile package will consist of a pre-cut, heavy paper pouch insert which supports the catheter in a [redacted] pouch. The device will contain a 3 year shelf life on the label. The submission indicates that the packaging was [redacted] (b)(4), and no evidence of [redacted] performance was detected. This testing information was [redacted] (b)(4)

D. **Is the device for single use?** Yes (section 7)
E. **Is the device for prescription use?** Yes

If yes, is prescription labeling included? No, the (b)(4) [redacted]

F. **Is the device for hospital, home, or portable use?** Hospital
Is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary? NA, device is a catheter introducer.

G. **Does the device contain drug or biological product as a component?** No

H. **Is this device a kit?** No
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? NA

I. **Soft-ware driven:** No
Estimated level of concern: (Major, Moderate, Minor)? NA
Has the firm provided hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices? NA
Software version: NA

J. **Electrically Operated:** No
If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? NA

K. **Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):** None
If applicable, has test data been provided to demonstrate conformance (protocol, data, and results) NA

L. **Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preAmendment status:**
Fast-Cath Transseptal Catheter Introducer by Daig (K911883)

M. **Submission provides comparative specifications:** Yes[a]
comparative <u>in vitro</u> data: Yes[b]
animal testing: No
clinical testing: No
biocompatibility testing: Yes[c]

[a]Section 6 includes catalogue information for predicate devices. (b)(4) [redacted]

[b]Section 12 of the submission includes performance testing information. The testing information includes (b)(4) [redacted]

(b)(4) test evaluated th (b)(4) [redacted]

(b)(4) testing was performed on (b)(4) [redacted]

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(b)(4)

(b)(4) test (b)(4)
(b)(4)

[c]The premarket notification (section 5) indicates that device materials and manufacturing processes are the same as those used in the currently marketed Daig Fast-Cath Transseptal Catheter Introducer (K911883). Biocompatibility testing information is included in section 9 of the submission. This testing information includes (b)(4) (b)
(b)(4)

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

This premarket notification submission addresses the addition of curve styles to the currently marketed line of Fast-Cath Transseptal Catheter Introducer (K911883). The Fast-Cath Transseptal Catheter Introducer is intended for use when introducing various cardiovascular catheters into the left side of the heart through the interartial septum.

The introducer is available with an 8F sheath and a 7.5F curved dilator. The introducer set consists of a radiopaque sheath and a dilator, each with curved distal portions to accommodate positioning in the cardiac anatomy. The introducer sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with 3-way stopcock is provided for air aspiration, fluid infusion, blood sampling, and pressure monitoring.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? No
If not, does the submission include a certification that such information will be made available to interested persons upon request? Yes (section 4)

Does the submission include the truthful and accurate statement? Yes (section 3)

Does the submission include the indications for use form? Yes (section 8), however, indications for use statement is not on the proper form.

If the device is substantially equivalent to a Class III device, does the submission include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) 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? NA

P. Request for additional information:

It is recommended that the following information be requested in a hold letter to the firm:

(b)(4)

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

Q. 510(k) Flow Chart

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

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS AS NEEDED (DELETE QUESTIONS WHICH ARE NOT APPLICABLE)

1. **IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE PRODUCT IS NOT A DEVICE.** The product under review in this file is a device.

2. **IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K).** This device is subject to a 510(k).

3. **IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION.** The Fast-Cath Transseptal Catheter Introducer is intended for use when introducing various cardiovascular catheters into the left side of the heart through the interartial septum. The currently marketed Fast -Cath Transseptal Catheter Introducer cleared in K911883 features the same indications for use statement.

4. **IF THE ANSWER TO QUESTION 4 IF YES OR NO, EXPLAIN WHY THERE IS/IS NOT A**

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NEW EFFECT OR SAFETY EFFECTIVENESS ISSUE. <>

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. <>

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS. <>

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH. <>

8. IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. <>

9. IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED. <>

10. IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED. <>

11. IF THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT.<>

R. RECOMMENDATION:

I believe additional information is necessary to address the above concerns.

Kimberly Bowie Peters, January 13, 1997
Division of Cardiovascular, Respiratory, &
Neurological Devices

(b)(4)

(b)(4)

REVISED:01/22/96

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K_____ Device Name_____

Division/Branch_____

Administrative Reviewer Signature_____Date_____

Supervisory Signature_____Date_____

Did the firm request expedited review? _____Yes_____No

Did we grant expedited review? _____Yes_____No

Truthful and accurate statement enclosed?_____Yes_____No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed?_____YES_____No
(Required for Original 510(k)s received 1/1/96 and after -- must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? _____Yes_____No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____Yes _____No

_____ Accepted

_____ Refuse To Accept

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I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☐	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☐
C. Is Device Subject To Review By CDRH?	☐	☐
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?:	☐	☐
1. Device Trade Or Proprietary Name	☐	☐
2. Device Common Or Usual Name Or Classification Name	☐	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☐	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☐	☐
5. Classification Panel	☐	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☐	☐

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	0	0
9. For Class III Devices Only, A Class III Certification And A Class III Summary	0	0
10. Photographs Of The Device	0	0
11. Engineering Drawings For The Device With Dimensions And Tolerances	0	0
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	0	0
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	0	0
14. Data To Show Consequences And Effects Of A Modified Device(s)	0	0
15. Truthful And Accurate Statement	0	0
II. Additional Information That Is Necessary Under 21 CFR 807.87(h):	0	0
A. Submitter's Name And Address	0	0
B. Contact Person, Telephone Number And Fax Number	0	0
C. Representative/Consultant If Applicable	0	0
D. Table Of Contents With Pagination	0	0
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	0	0
III. Additional Information That May Be Necessary Under 21 CFR 807.87(h):	0	0
A. Comparison Table Of The New Device To The Marketed Device(s)	0	0
B. Action Taken To Comply With Voluntary Standards	0	0
C. Performance Data	0	0
MARKETED DEVICE:	0	0
Bench Testing	0	0
Animal Testing	0	0
Clinical Data	0	0
NEW DEVICE:	0	0
Bench Testing	0	0
Animal Testing	0	0

Records and Data		
D. Sterilization Information	0	0
E. Software Information	0	0
F. Hardware Information	0	0
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	0	0
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	0	0
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	0	0
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	0	0
I. Other (Specify)	0	0

REVISED: 3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

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

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

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

1. Intended Use:

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

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics ar not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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

November 12, 1996

DAIG CORP.
14901 DEVEAU PLACE
MINNETONKA, MN 55345
ATTN: JOHN C. HEINMILLER

510(k) Number: K964518
Received: 25-OCT-96
Product: FAST-CATH
TRANSSEPTAL CATHETER
INTRODUCER

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

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

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

K964518

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 10·28·96

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s) ~~K911883~~/A1

To: Division Director, CV/ACRND

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission. 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. Feel free to note any additional comments below.

Thank you for your cooperation.

______ Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY 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 the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE K30 LETTER ON THE LAN.]

✓ Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(K)].

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

COMMENTS: ______________________________

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

Reviewed by: Judy Danielson

Date: 11/5/96

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CV #

DAIG
a St. Jude Medical Company

October 24, 1996

Hand Delivered via Federal Express P-1

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

Re: FAST-CATH™ TRANSSEPTAL CATHETER INTRODUCER
510(K) SUPPLEMENT TO DOCUMENT CONTROL NO. K911883
Establishment Registration No. 2182269

Dear FDA Representative:

Enclosed is Daig Corporation's 510(k) supplement covering its request to add curve styles to its line of Fast-Cath™ Transseptal Catheter Introducer. Fast-Cath™ Catheter Introducers are cleared for marketing under Document Control Number K911883. Daig Corporation is now filing this 510(k) supplement in support of additional curve styles.

Daig Corporation underwent a routine GMP audit by FDA on May 1, 1996. There were no 483 Reports issued as a result of that audit.

Daig Corporation regards its' intent to market the FAST-CATH™ TRANSSEPTAL CATHETER INTRODUCER as confidential information and requests that the Food and Drug Administration not disclose this notification for at least ninety (90) days or until commercial distribution begins.

Sincerely,

DAIG CORPORATION

John C. Heinmiller
Official Correspondent

JCH:jlb

Enclosures (2)

DAIG CORPORATION 14901 DeVeau Place Minnetonka, MN 55345-2126 USA (612) 933-4700 (800) 328-3873

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CV II

DAIG
A St. Jude Medical Company

510(k) Supplement

Fast-Cath™ Transseptal Catheter Introducer

Supplement to 510(k)
Document Control No. K911883

Establishment Registration No. 2182269

Daig Corporation
14901 DeVeau Place
Minnetonka, MN 55345-2126
Tel. (612) 933-4700

October 24, 1996

Vol. 1 of 1

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510(k) Supplement
Fast-Cath™ Transseptal Catheter Introducer

Table of Contents

General Information

Submitter's Name and Address:

Daig Corporation
14901 DeVeau Place
Minnetonka, MN 55345-2126

Contact Person:

John C. Heinmiller
(612) 933-4700 Ph
(612) 930-9481 Fax

Address of Manufacturing Facility and Sterilization Facility:

Daig Corporation
14901 DeVeau Place
Minnetonka, MN 55345-2126

Establishment Registration Number:

2182269

Common Name: Transseptal Catheter Introducer

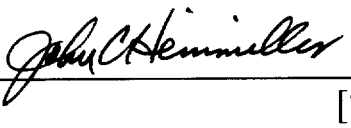
Classification Name: Introducer

Device Proprietary Name: Fast-Cath™ Transseptal Catheter Introducer

Class of Device/Devices: The Circulatory System Device Panel has classified these devices as Class II.

Premarket Notification
Truthful and Accurate Statement
(as required by 21 CFR 807.87(j))

I certify that, in my capacity as the Official Correspondent for Regulatory Affairs of Daig Corporation, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



[Signature]

John C. Heinmiller Official Correspondent for Regulatory Affairs
[Typed Name and Title]

Daig Corporation October 24, 1996
[Company] [Date]

[*Premarket Notification (510(k)) Number*]

510(k) Statement

I certify that, in my capacity as official Correspondent of Daig Corporation, I will make available all information included in this pre-market notification on safety and effectiveness within 30 days of request by any person if the device described in the pre-market notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the pre-market notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Signature: John C Heinmiller

Name: John C. Heinmiller

Title Official Correspondent

Date: October 24, 1996

510(k) Supplement Rationale

Daig Corporation has authority to market its Fast-Cath™ Transseptal Catheter Introducer covered under Document Control Number K911883, dated April 16, 1992.

Daig now requests authorization to market additional curve styles of the transseptal sheath introducer.

This filing includes biocompatibility testing performed on the patient contacting material (even though this material is not changing from the material cleared for use under other Daig 510(k) files, it is included herein for ease of reference) and performance testing conducted on the additional curve styles (for your reference, tabs for these sections have been appropriately labeled).

Identification of Legally Marketed Equivalent Devices

Daig previously supplied as part of its application under Document Control Number K911883 the Instructions for Use and Package Labeling for equivalent devices currently sold in the United States by other manufacturers.

For reference purposes, information regarding equivalent devices currently sold in the United States by the USCI division of C.R. Bard, the Mansfield division of Boston Scientific Corporation, and by Cook Incorporated are included in this section on the succeeding five (5) pages.

Transseptal Catheter Introducer Sheaths

General Characteristics:

Color coding provides easy French size identification.

Supplied sterile.

Items per box: 1.

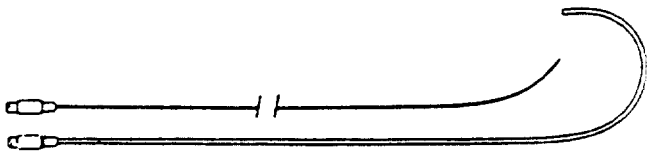
Product Description:

Offers flexibility in gaining access to the left atrium from the venous system.

FEP sheath.

FEP dilator.

Used with curved Brockenbrough* Needle, see page 9-17.



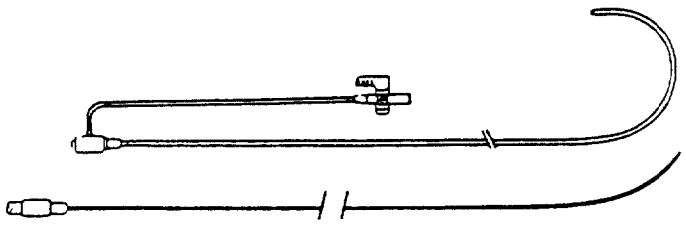
Mullins™ Transseptal Catheter Introducer Sheaths Adult and Pediatric Lengths

Catalog Number	French Size	Maximum Wire Size (in)	Sheath Length (cm)	Dilator Sheath (cm)	Each Price
008550	6	.032	59	67	$85.00
008551	7	.032	59	67	85.00
008552	8	.032	59	67	85.00

For use with adult curved Brockenbrough Needle #003994

008530	6	.025	44	52	$85.00
008531	7	.025	44	52	85.00
008532	8	.025	44	52	85.00

For use with adult curved Brockenbrough Needle #003994



USCI Transseptal Catheter Introducer Sheaths with Hemostasis Valve

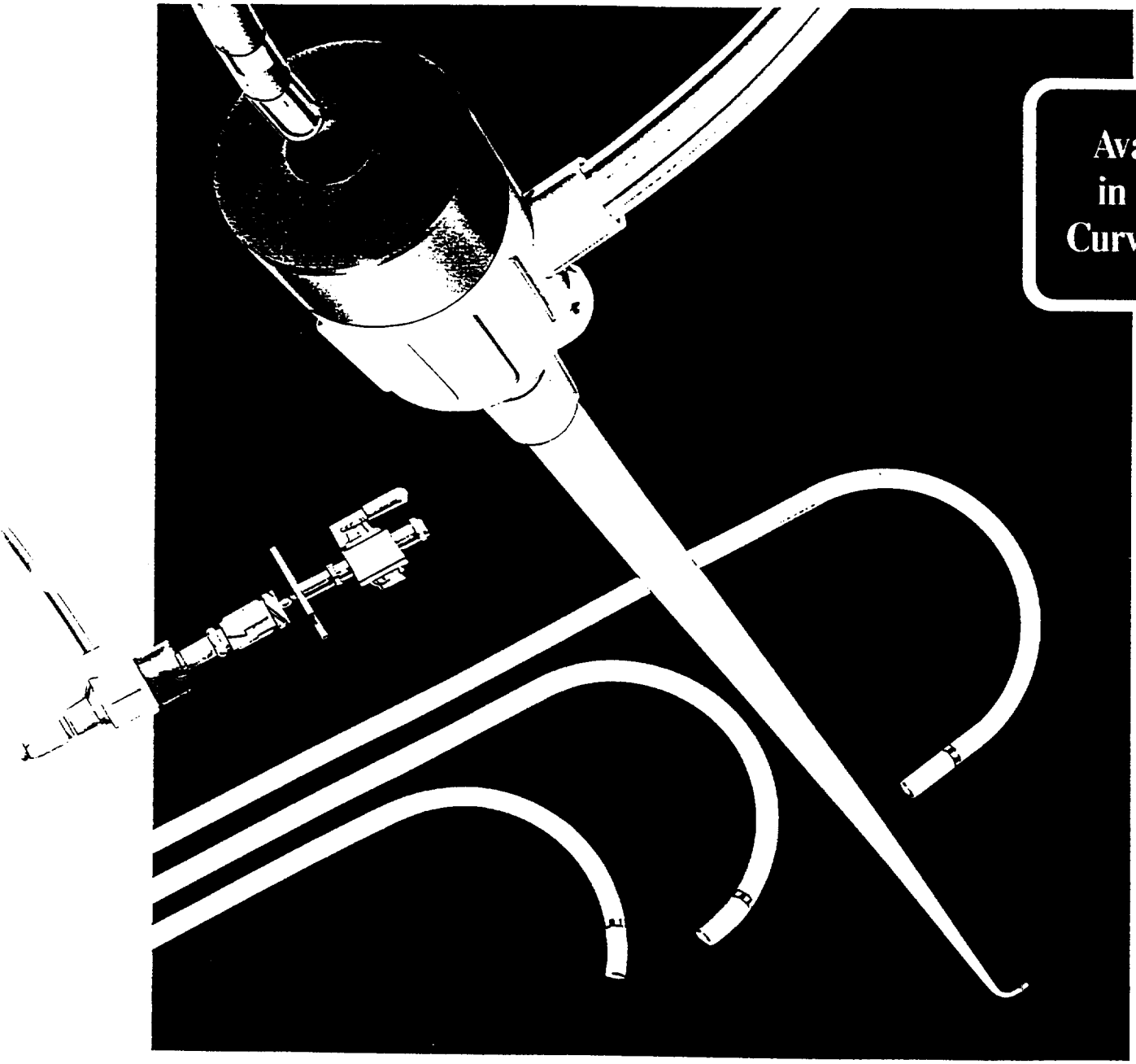
008591	8	.032	59	67	$90.00

For use with adult curved Brockenbrough Needle #003994

This symbol represents USCI Pediatric Products.

KLEIN™

Transseptal Introducer Sheath



Available in Three Curve Styles

Designed Specifically for Left-Sided EP Procedures

Mansfield® EP

Boston Scientific Corporation

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KLEIN™

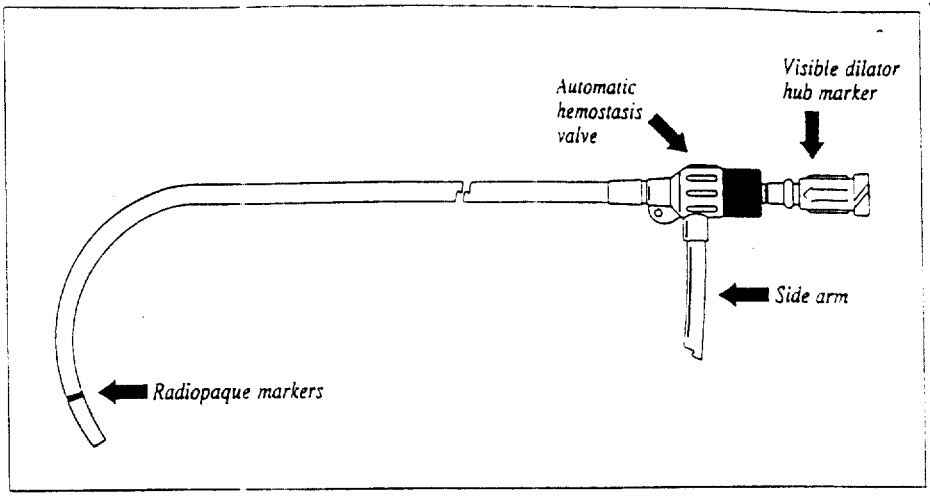
Transseptal Introducer Sheath

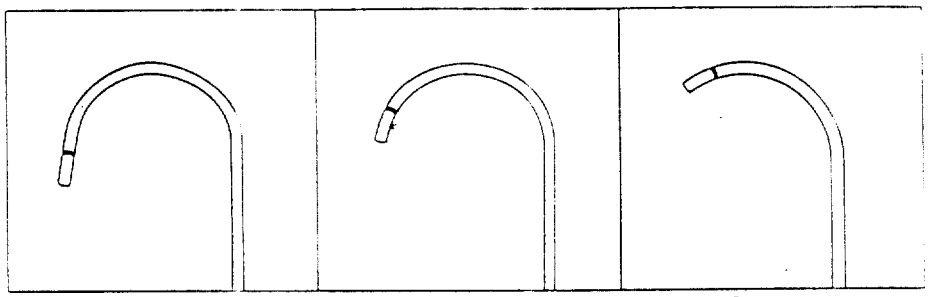
Simplified positioning with increased catheter control.

Designed by a noted electrophysiologist specifically for EP procedures, the Klein Transseptal Introducer Sheath facilitates access to the left atrium. The three available curve styles direct and position the EP catheter to the desired location, for mapping the left side of the heart.

Advantages

- Radiopaque marker allows tip visualization while positioning and maintaining the sheath across the septum.
- Long sheath enhances EP catheter stability, torque transmission, coaxial steering, and catheter positioning.
- The direction of the sidearm dictates proper sheath curve orientation.
- Visible dilator hub marker indicates the direction of the curve for improved sheath positioning.
- Automatic hemostasis valve design prevents air entry and back-bleeding.
- Lubricious coating eases insertion and enhances catheter movement.





Standard Reach Curve *Medium Reach Curve* *Short Reach Curve*

Ordering Information: (800) 225-2732

Order Number	Description	Size (Fr)	Sheath Length (cm)	Guidewire Specifications
5650	Standard Reach Curve	8	60	.038" x 135cm
5651	Medium Reach Curve	8	60	.038" x 135cm
5652	Short Reach Curve	8	60	.038" x 135cm

Packaged 3 per box.

The Klein Transseptal Introducer Sheath was designed in collaboration with George Klein, M.D . F.R.C.P., University Hospital, London, Ontario, Canada.

Mansfield EP designs and manufactures an extensive selection of catheters, accessories and complementary products for EP procedures.

For more information on Mansfield EP products, please contact your Mansfield EP Product Specialist or Customer Service Representative.

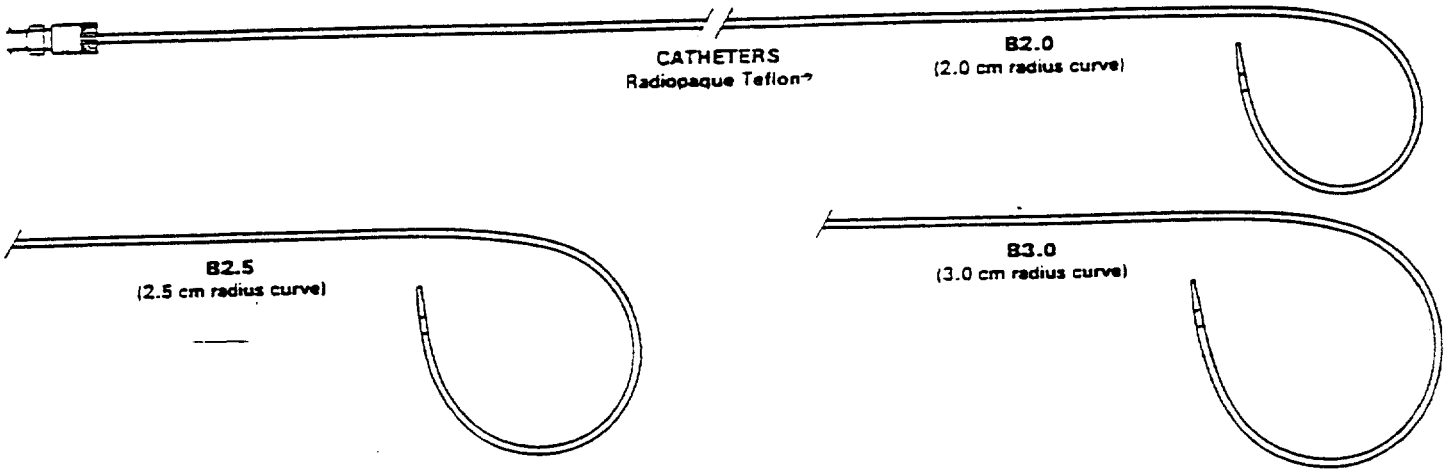
Mansfield™ EP

Boston Scientific Corporation
480 Pleasant Street Watertown, MA 02172
(617) 923-1720

CCCK

BROCKENBROUGH TRANSSEPTAL LEFT HEART CATHETERS

Used for transseptal left heart catheterization. The catheters are manufactured to fit the Transseptal Needle Set described below. NOTE: Removal of the female Luer lock portion of the catheter hub is necessary to properly fit the catheter to the needle. The catheter will accept .038 inch (0.97 mm) diameter wire guide. Supplied sterile in peel-open packages. Intended for one-time use.



Not to scale

TO ORDER, FOLLOW THE ARROWS: (Example: T7.0-38-70-M-4S-B2.0)

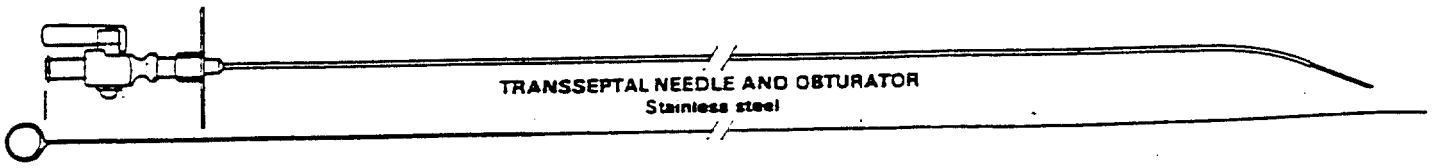
[2] - [3] [4] [5] [6]

ORDER NUMBER PREFIX FRENCH SIZE	WIRE GUIDE DIAMETER inches millimeters .038 0.97	LENGTH cm	FITTING Metal Luer lock	SIDE-PORTS	TIP CONFIGURATION
T7.0	38	70	M	4S[1]	B2.0 B2.5 B3.0
T8.0	38	70	M	4S	B2.0 B2.5 B3.0

[1] 4S = 4 sideports

TRANSSEPTAL NEEDLE SET

Used for transseptal left heart access. Used in conjunction with the transseptal catheters described above. Supplied sterile in peel-open packages. Intended for one-time use.



SET ORDER NUMBER	TRANSSEPTAL NEEDLE Proximal Gage	Distal Tip Gage	Length	Remarks
NC-18-71	18	21	71 cm	For adults

$46.00

REFERENCES

E. C. Brockenbrough, E. Braunwald: "New Technique for Left Ventricular Angiocardiography and Transseptal Left Heart Catheterization," *American Journal of Cardiology*, 6:1064.

C. R. Conti, W. Grossman: "Percutaneous Approach and Transseptal Catheterization," in W. Grossman: *Cardiac Catheterization and Angiography*, Second Edition, Lea and Febriger, 1980.

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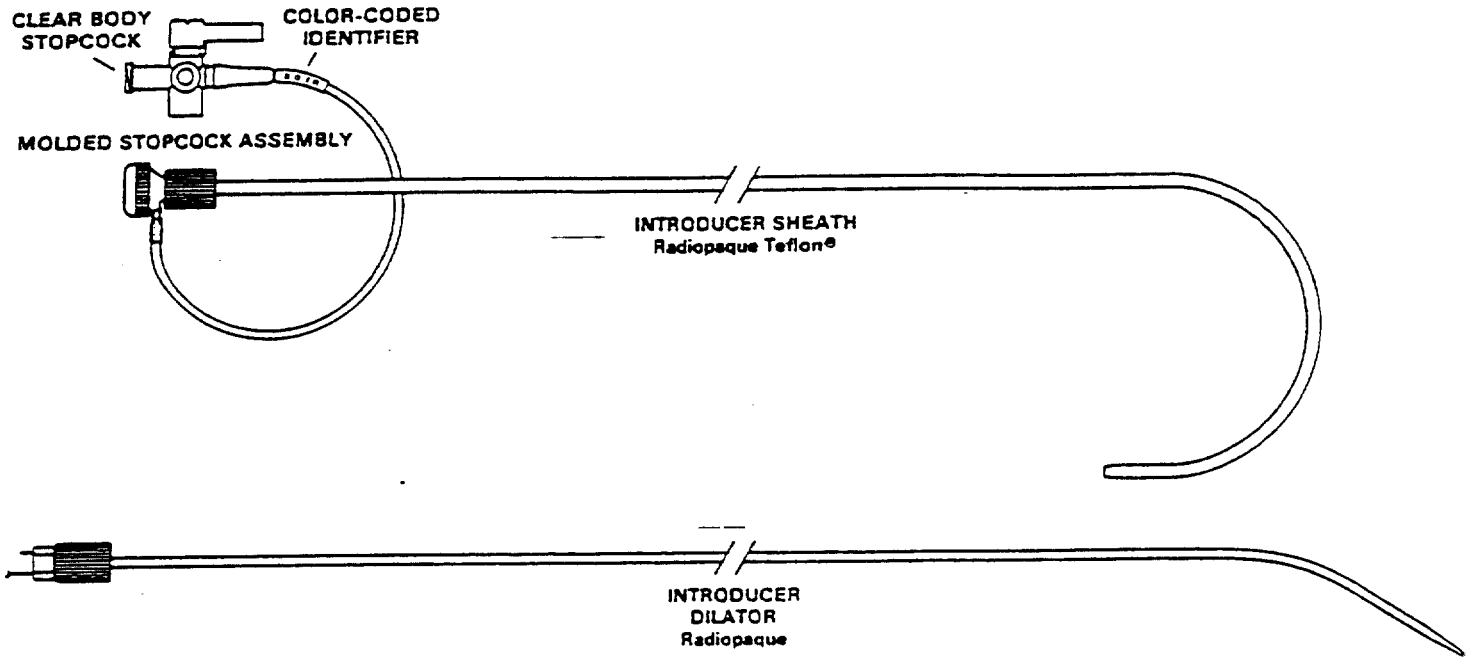
COOK

CHECK-FLO® II BLUE INTRODUCER SETS

MULLINS TYPE

Used to introduce balloons, closed and non-tapered end catheters and other devices for intervention. The unique Teflon® sheath material increases flexibility and maintains curve retention during procedural use. The Check-Flo® II valve prevents blood reflux and air aspiration. The side-arm fitting allows flushing around the catheter while it is positioned inside the sheath. The side-connection line can be used as a second infusion line. **The maximum diameter of the device or catheter to be introduced should be determined to insure its passage through the sheath.**[1] Supplied sterile in peel-open packages. Intended for one-time use.



TO ORDER, FOLLOW THE ARROWS: (Example: RCFW-6.0-38-63-MTS)

[1] SET[2] ORDER NUMBER PREFIX	[2] FRENCH SIZE OF INTRODUCER [1]Maximum Diameter of Instrument To Be Introduced	[3] WIRE GUIDE DIAMETER inches millimeters .038 0.97	[4] SHEATH LENGTH cm	[5] TIP CONFIGURATION
RCFW	6.0 7.0 8.0 8.5	38	63 85	MTS
		18T Fits Needle Gage		

[2]Wire guide not included.

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Proposed Labeling

Enclosed in this section are the proposed package label and instructions for use manual for the additional curve styles of the transseptal catheter introducer.

Fast-Cath™ Transseptal Catheter Introducer
Example of Pouch Label

DAIG
a St. Jude Medical Company

FAST-CATH™ 8F

TRANSSEPTAL INTRODUCER
TRANSSEPTALES EINFÜHRUNGSGERÄT
INTRODUCTEUR TRANSSEPTAL
INTRODUTTORE TRANSETTALE
INTRODUCTOR TRANSEPTAL
トランスセプタル用カテーテルシースセット

AMAS 1-2™ Curve w/Tip Marker

Reorder No. Katalog-Nr. No. du Catalogue No. di Codice Nuevo pedido No. リオーダ No.	Length Länge Longueur Lunghezza Longitud 長さ	Max. Guidewire O.D. Mandrin A.D., max. D.E. max. du Guide D.E. max. della Guida D.E. máx. de la guía ガイドワイヤ最大外径
408131	69 cm	.038

Lot No. Chargen-Nr. Lot No. Lotto Nr. Lote No. ロットNo.	Sterilized On Sterilisiert am Date de stérilisation Data di sterilizzazione Fecha de esterilización 滅菌年月日	Use Before Verwendbar bis A utiliser avant Da utilizzare entro Uselo antes del 使用有効期限
XXXXXX	XXXXXXX	XXXXXXX

Contents
Inhalt
Contenu
Contenuto
Contenido
内容品

8F Sheath
7.5F Curved Dilator 74 cm

CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE.

U.S. Patent Nos. 4,909,798 & 5,092,857 and Patent(s) Pending

+H68440813118

CE 0044

40959 Rev. A

DAIG CORPORATION
Minnetonka, MN 55345-2126 USA
612-933-4700 800-328-3873
FAX: (612) 933-0307

40894-031 Rev. E

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DAIG **INSTRUCTIONS FOR USE**

FAST-CATH™

TRANSSEPTAL CATHETER INTRODUCER WITH HEMOSTASIS VALVE

SEE PRODUCT CATALOG FOR PRODUCT REORDER NUMBERS AND SPECIFICATIONS.

Read Instructions for Use prior to use of this device.

SEE INDIVIDUAL STERILE PACKAGE LABEL FOR CONTENTS.

SINGLE-USE DISPOSABLE MEDICAL DEVICE.
CONTENTS ARE STERILE IF PACKAGE IS UNOPENED AND UNDAMAGED.
DO NOT RESTERILIZE.

1 of 4

INDICATIONS

When introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

CONTRAINDICATIONS

- Previous intra-atrial septal patch.
- Previous systemic embolization from the left side of the heart.
- Known or suspected left atrial myxoma.
- Myocardial Infarctions within the last two weeks.
- Unstable angina.
- Recent Cerebral Vascular Accident (CVA).
- Patients who do not tolerate anticoagulation therapy.
- Patients with an active infection.

PRECAUTIONS

- Inspect all components before use.
- Federal (U.S.A.) law restricts this device to use by or on the order of a physician.
- The french size specified represents the inner diameter of the introducer sheath.
- Do not attempt to insert a catheter having a distal tip or body size larger than the introducer size indicated.
- The Daig hemostasis introducer is designed to interlock only with Daig dilators. Misuse may result in serious complications.
- Do not attempt to use a guidewire over maximum diameter specified on package label.
- Carefully reading the Instructions before use of this device will help to reduce the potential dangers associated with the transseptal technique such as emboli and/or perforation of the aorta and left atrium.
- Prior to inserting the device into the patient, pre-assemble the sheath and dilator.
- During insertion, use caution not to create excessive bends in this device.
- Frequently aspirate and saline flush the sheath to minimize the potential for emboli.
- Do not remove dilator or catheter rapidly. Damage to the backbleed valve may occur.
- If resistance is met when advancing or withdrawing guidewire or introducer, determine cause and correct before continuing with this procedure.
- Indwelling percutaneous introducer sheaths should always be supported with a catheter.
- Aspirate only from the sideport.
- Inject or saline flush only from the sideport.

- Certain conditions may require special consideration when using this product. These may be, but are not limited to: Enlarged Aortic Root, Small Left Atrium, Marked Right Atrial Enlargement, Marked Distortion of the Thorax Configuration (i.e. Kyphosis or Scoliosis).
- Store in a cool, dark, dry place.

WARNINGS

- Do not alter this device in any way.
- **Only those physicians who are specially trained in transseptal procedures and Daig catheter delivery systems should use this device.**
- Do not reuse this device. Thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device.
- Maintain continuous pressure monitoring throughout the procedure.
- Maintain anterior-posterior and lateral fluoroscopy throughout the procedure.
- Always observe acceptable pressure tracings prior to advancing the dilator or any other component.
- Do not create a vacuum in the sheath. Remove components and make catheter exchanges slowly.
- From the sideport only—aspirate all air prior to infusion.
- Provide a continuous drip under pressure when the introducer remains in the vessel.
- Fibrin may accumulate in or on the sheath tip during the procedure. Aspirate when removing dilator or catheter.
- Reinsert the dilator fully into the introducer sheath to aid in straightening the tip portion. Then remove the dilator and introducer sheath as a unit.

DESCRIPTION

The Daig Transseptal Catheter Introducer Set consists of a radiopaque sheath and a dilator each with specially curved distal portions to accommodate positioning in the cardiac anatomy. The introducer sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air aspiration, fluid infusion, blood sampling and pressure monitoring.

SUGGESTED PROCEDURE

- To determine size and location of left atrium and atrial septum, it may be helpful to perform right side angiography.
- Obtain a Daig Transseptal Catheter Introducer Set designed for a Brockenbrough type curved puncture needle.

  CAUTION: Observe the precautions specified in the instructions provided with the Daig Transseptal Catheter Introducer.
- Thoroughly flush sheath thru the sideport, filling sheath column with saline.
- Thoroughly flush dilator, filling dilator column with saline.
- Assemble the dilator and sheath and "snap" the dilator into the sheath hub.
- Once dilator is fully positioned in sheath, introduce additional saline through the sideport to ensure air is removed from the area between dilator and sheath.

- Position an .032" diameter guidewire well into the Superior Vena Cava (SVC).
- Introduce the dilator/sheath assembly as a unit over the guidewire.
- Advance the dilator/sheath assembly into the Superior Vena Cava (SVC) just above the right atrium. Verify with fluoroscopy.
- Separate the snap-lock hubs of the dilator and sheath and slowly advance the sheath 1 cm as shown by the proximal markings on the dilator body.
- Remove the guidewire.
- Allow blood to aspirate in order to clear dilator of any possible air. Flush as required.
- Thoroughly flush long, curved septal puncture needle.
- Pass the needle into the dilator and advance the curved distal portion past the sheath hub. The separation of dilator and introducer hubs better accommodates the introduction of the curved septal puncture needle.
- Allow the needle to move freely as the curved distal portion passes through the dilator and introducer hubs.
- Reattach the dilator hub and introducer hub.
- Slowly advance the needle into the dilator so that the needle tip is within the tip of the dilator.

  NOTE: Make sure the needle is free to twist and/or rotate without resistance as it is advanced to this position.
- Connect the needle hub to pressure monitoring equipment. Make sure that good atrial pressure is observed prior to proceeding.
- Slowly withdraw the needle, sheath and dilator as an assembly from the Superior Vena Cava, allowing the assembly to curve toward and position themselves in the right atrium and against the atrial septum in the region of the fossa ovalis. Use gradual rotation of the needle posteriorly and toward the left scapula during this withdrawal.

  NOTE: Continual pressure monitoring and repeated anterior-posterior and lateral fluoroscopic monitoring during any positioning cannot be overemphasized.
- Proceed with the transseptal puncture and advance the needle.

  You will experience a slight buildup of resistance followed by a sudden release of back pressure as the needle passes through the septum and enters the left atrium.
- Confirm with pressure monitoring.

  CAUTION: Immediately following penetration of the interatrial septum, observe acceptable left atrial pressure on the pressure monitoring equipment.

  NOTE: Remove the pressure monitoring line and slowly inject a small volume of contrast medium through the needle to identify the area of penetration in the septum or wall of the left atrium.
- Advance the dilator with the needle through the septum by using firm but not undo pressure. Continue to observe acceptable atrial pressure. You should experience a slight release of back pressure as the dilator penetrates the septum.
- Using fluoroscopy, withdraw the needle to a point just inside the dilator tip. Position the dilator/needle freely in the left atrium.
- Advance the sheath over the dilator into the left atrium.

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NOTE: Continue to observe that the needle is located within the dilator tip.

NOTE: Rotate the sheath back and forth while applying slight forward pressure, a release of which is felt as the sheath penetrates the septum.

- Remove the pressure monitoring line from the needle.
- Withdraw the needle slowly from the dilator.
- Remove the dilator.

CAUTION: Always withdraw components slowly to minimize the vacuum created during withdrawal.

- Reattach the monitoring line to the inner sheath sideport.
- Aspirate the inner sheath through the sideport for sampling purposes.

CAUTION: If the inner sheath tip has been withdrawn into the outer sheath, the outer sheath tip may be resting against the atrium or pulmonary vein as evidenced by a lack of free-flowing blood. Rotate the sheath assembly or withdraw the assembly 1/2 to 1 cm and reestablish blood flow.

- Note the distance of the outer sheath hub from the puncture site.
- Follow manufacturer's recommendations for the catheter or device being introduced via the hemostasis introducer.

CAUTION: Care should be taken to ensure the distal tip portion of the sheath assembly remains across the septum and well into the left atrium.

- **Reinsert the dilator fully into the introducer sheath to aid in straightening the tip portion. Then remove the dilator and introducer sheath as a unit.**

NOTE: If the larger lumen Daig Transseptal Catheter Introducer is being used in combination with a longer and smaller lumen Daig Transseptal Catheter Introducer as an "inner/outer" set, the following applies.

- Advance an .032" diameter guidewire through the dilator, across the septum and well into the left atrium. Verify with fluoroscopy.

NOTE: Repeated anterior-posterior and lateral fluoroscopic monitoring during any positioning cannot be overemphasized.

- Withdraw the dilator/sheath assembly as a unit leaving the guidewire in position in the left atrium.

CAUTION: Always withdraw components slowly to minimize the vacuum created during withdrawal.

- Assemble the dilator into the inner sheath. Assemble the dilator/inner sheath assembly into the outer sheath.
- Introduce the two (2) piece sheath and dilator assembly as a unit over the guidewire.
- Slowly aspirate all air from each sheath using a syringe attached to one of the ports of each of the three-way stopcocks.

NOTE: Provide a pressurized saline flush through the sideport.

- Advance the two (2) piece sheath and dilator assembly over the guidewire into the right atrium, through the septum and into the left atrium. Verify with fluoroscopy.
- Remove the guidewire.
- Remove the dilator.

CAUTION: Always withdraw components slowly to minimize the vacuum created during withdrawal.

- Reattach the monitoring line to the inner sheath sideport.
- Aspirate the inner sheath through the sideport for sampling purposes.

  CAUTION: If the inner sheath tip has been withdrawn into the outer sheath, the outer sheath tip may be resting against the atrium or pulmonary vein as evidenced by a lack of free-flowing blood. Rotate the sheath assembly or withdraw the assembly 1/2 to 1 cm and reestablish blood flow.
- Note the distance of the outer sheath hub from the puncture site.
- Follow manufacturer's recommendations for the catheter or device being introduced via the hemostasis introducer.

  CAUTION: Care should be taken to ensure the distal tip portion of the sheath assembly remains across the septum and well into the left atrium.
- **Reinsert the dilator fully into the introducer sheath to aid in straightening the tip portion. Then remove the dilator and introducer sheath as a unit.**

LIMITED WARRANTY AND DISCLAIMER

Daig Corporation ("Daig") hereby warrants that if any Daig product fails to perform within normal tolerances for a patient due to a defect in materials or workmanship, Daig will provide, at no charge, a replacement Daig product for the patient's use. This limited warranty applies only if each of the following conditions are met.

1. The product was packaged and labeled by Daig.

2. The failed product must be returned to Daig and becomes the property of Daig.

3. The product has not been mishandled, reprocessed or altered in any way.

4. The product was used before the "USE BEFORE" date marked on the packaging of the product.

No representation or warranty is made that a Daig product will not fail. Daig disclaims responsibility for any medical complications, including death, resulting from the use of its products. Except as expressly provided by this limited warranty, DAIG IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUNCTION OF ITS PRODUCTS, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE. Some states do not allow the exclusion or limitation of incidental or consequential damages however, so the above limitation or exclusion may not apply to you.

Except as expressly provided by the limited warranty, DAIG MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

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Intended Use of Proposed Device

Daig Fast-Cath™ Transseptal Catheter Introducers are designed for use when a procedure involves introducing various cardiovascular catheters into the left side of the heart.

Biocompatibility Tests

Biocompatibility testing has been performed on the (b)(4) **materials** and the results of each test are included behind the indicated index tab as follows:

Description of Test	Index Tab Label
(b)(4)	(b)(4)

The above tests include all those suggested by American National Standard ANSI/AAMI 10993-1 for this device and duration category. In addition to the tests suggested by the above standard, Daig has performed (b)(4) testing, (b)(4) (b)(4)

All of the above tests conclude that the (b)(4) **materials** are biologically compatible.

(b)(4) Third Party Testing

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Packaging and Sterilization

Sterile packaging for the Fast-Cath™ Transseptal Catheter Introducer will be the same as all other Daig product packaging. The sterile package will consist of a pre-cut, heavy paper pouch insert (card) which supports the catheter in a (b)(4) pouch with labels. As part of a (b)(4) (b)(4) test, Daig packages were (b)(4). No evidence of unacceptable (b)(4) was detected. The Fast-Cath™ Transseptal Catheter Introducer will contain a 3 year shelf life on the label.

Prior to bench testing and as part of a complete record of data collection, the devices are sterilized using the standard sterilization cycle used for all Daig manufactured devices. This cycle will be used for the Fast-Cath™ Transseptal Catheter Introducer.

The sterilization parameters are currently as follows: (b)(4) (b)(4) (b)(4). These sterilization parameters were established in accordance with guidelines in ANSI/AAMI ST27-1988 and ANSI/AAMI ST34-1991 standards.

Sterility performance is established per U.S.P. XXII sterility release criteria. In addition, (b)(4) Test and (b)(4) Test are performed per U.S.P. XXII on each sterilization lot.

(b)(4) is performed (b)(4) (b)(4) All results are compared to the limits set forth by the Federal Register Proposed Rules, Volume 43, No. 122, Friday, June 23, 1978 for devices contacting blood (ex vivo).

Fast-Cath™ Transseptal Catheter Introducer

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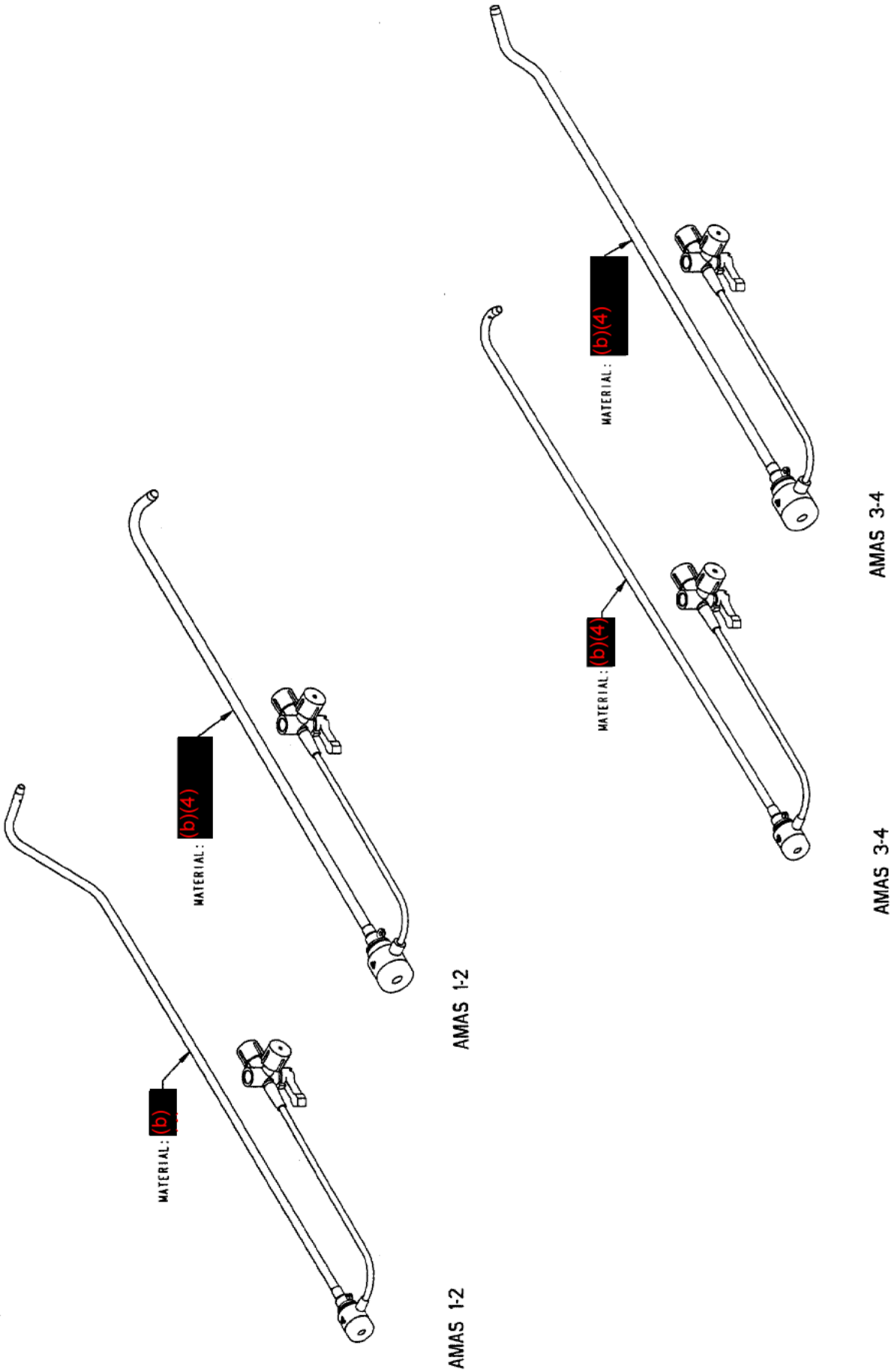
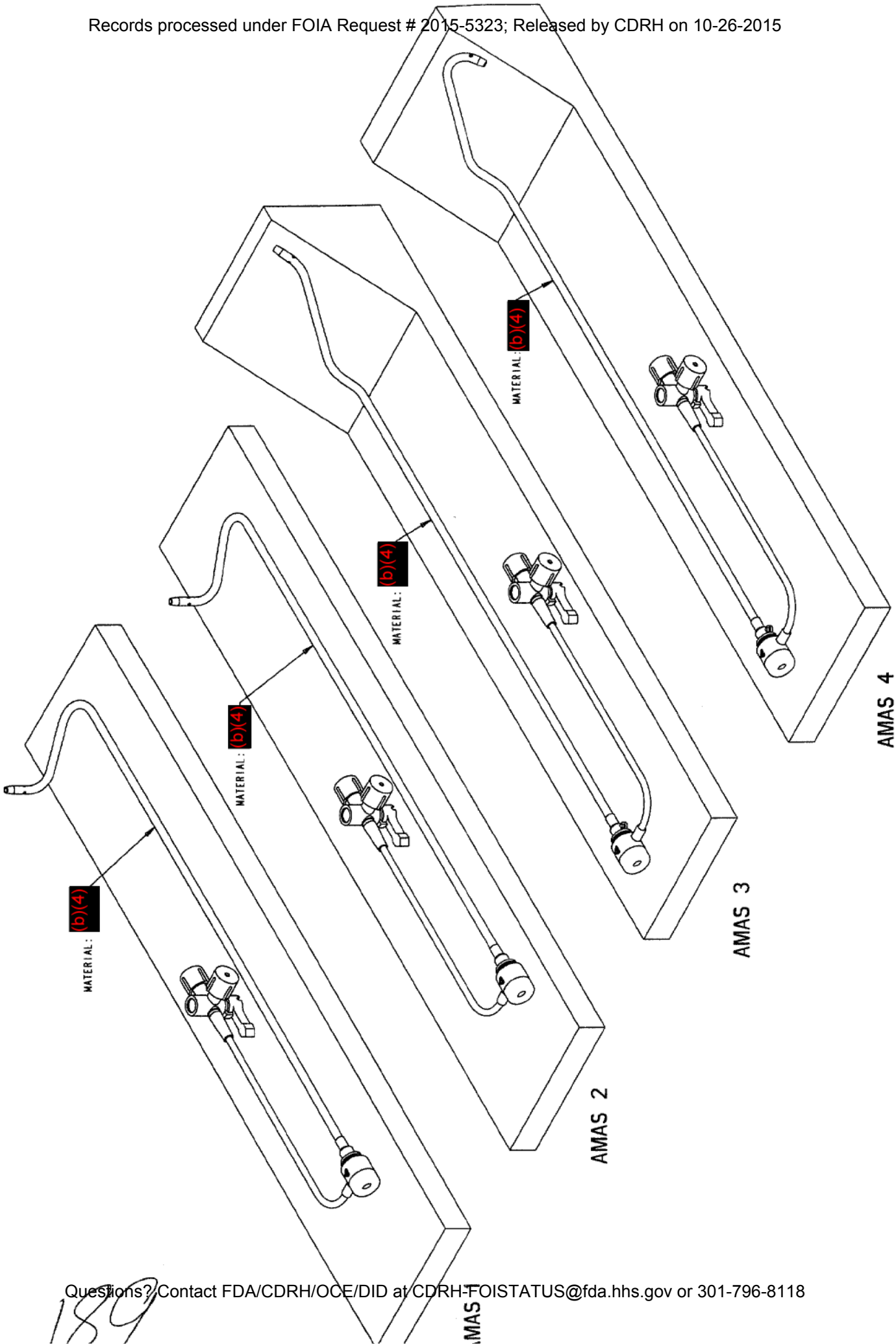
Introducer Shapes and Specifications

Daig plans to market a complete line of transseptal catheter introducers having a variety of distal curve styles. The materials and manufacturing process used by Daig to produce each curve type and diameter (French size) is identical. A representative sample of curve styles is presented on the next two pages.





Fast-Cath™ Transseptal Catheter Introducer

—

Performance Data

Daig plans to market a complete line of transseptal catheter introducers having a variety of distal curve styles. The materials and manufacturing process used by Daig to produce each curve type and diameter (French size) is identical. The example curve styles depicted in the diagrams provided in Section 11 were subjected to a set of tests designed to document the performance of Daig's transseptal catheter introducers.

The test protocols, results of tests, analysis of results, and conclusions are presented on the next twenty-nine (29) pages.

Purpose: The purpose of the following set of tests is to document the product performance of the AMAS sheath system. These tests include (b)(4)

(b)(4)

Results:

(b)(4)

Analysis of Results: (b)(4)

(b)(4)

Conclusions: (b)(4)

(b)(4)

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Purpose: (b)(4) Testing

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Protocol: (b)(4) Testing

Results:

Analysis of Results:

Conclusion:

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Analysis of Results:

Conclusion:

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Testing

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Protocol:

(b)(4) Testing

Results:

Analysis of Results:

Conclusion:

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Protocol:

Results:

Analysis of Results

Conclusion:

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Purpose: (b)(4) Testing

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Analysis of Result

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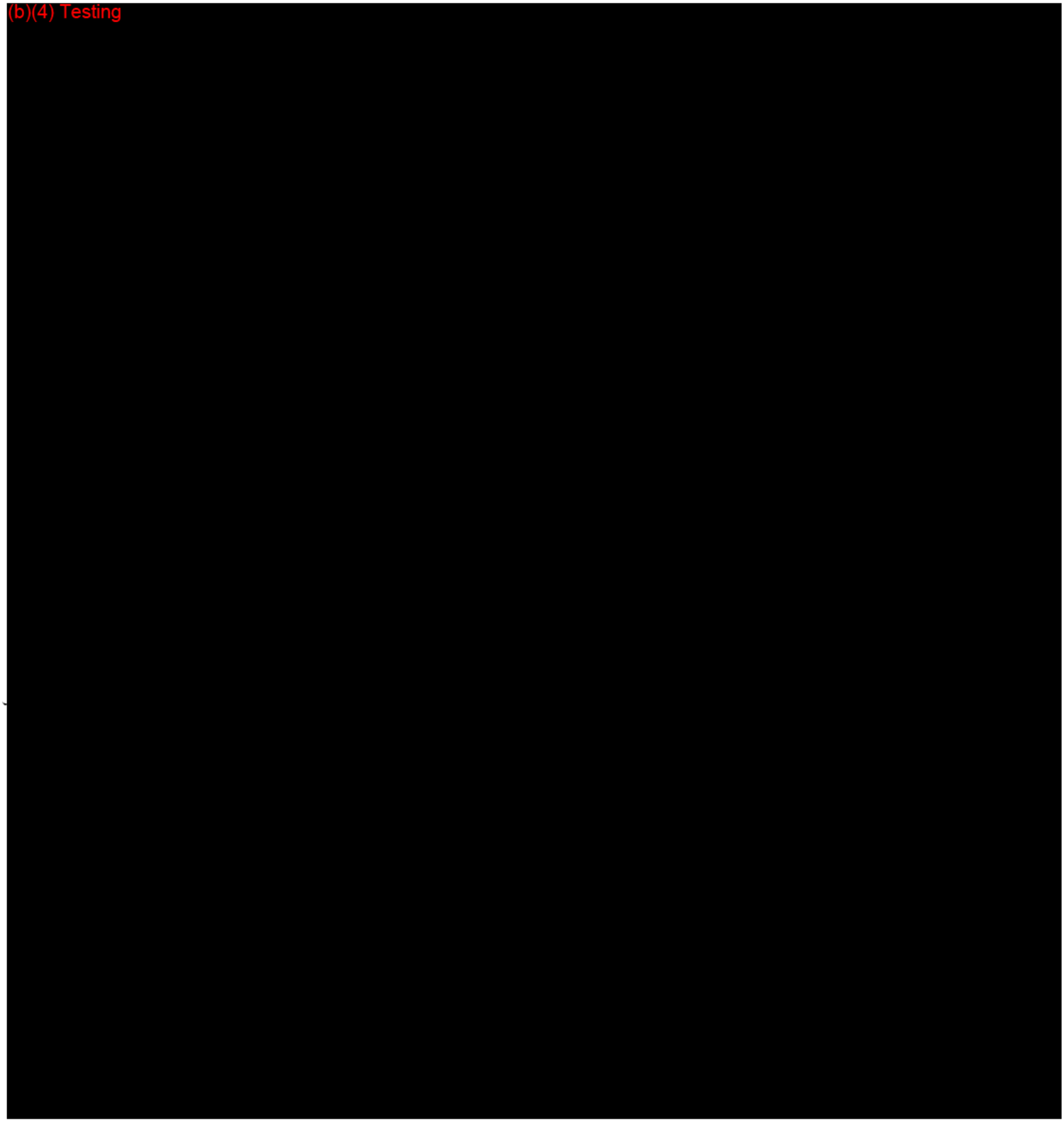

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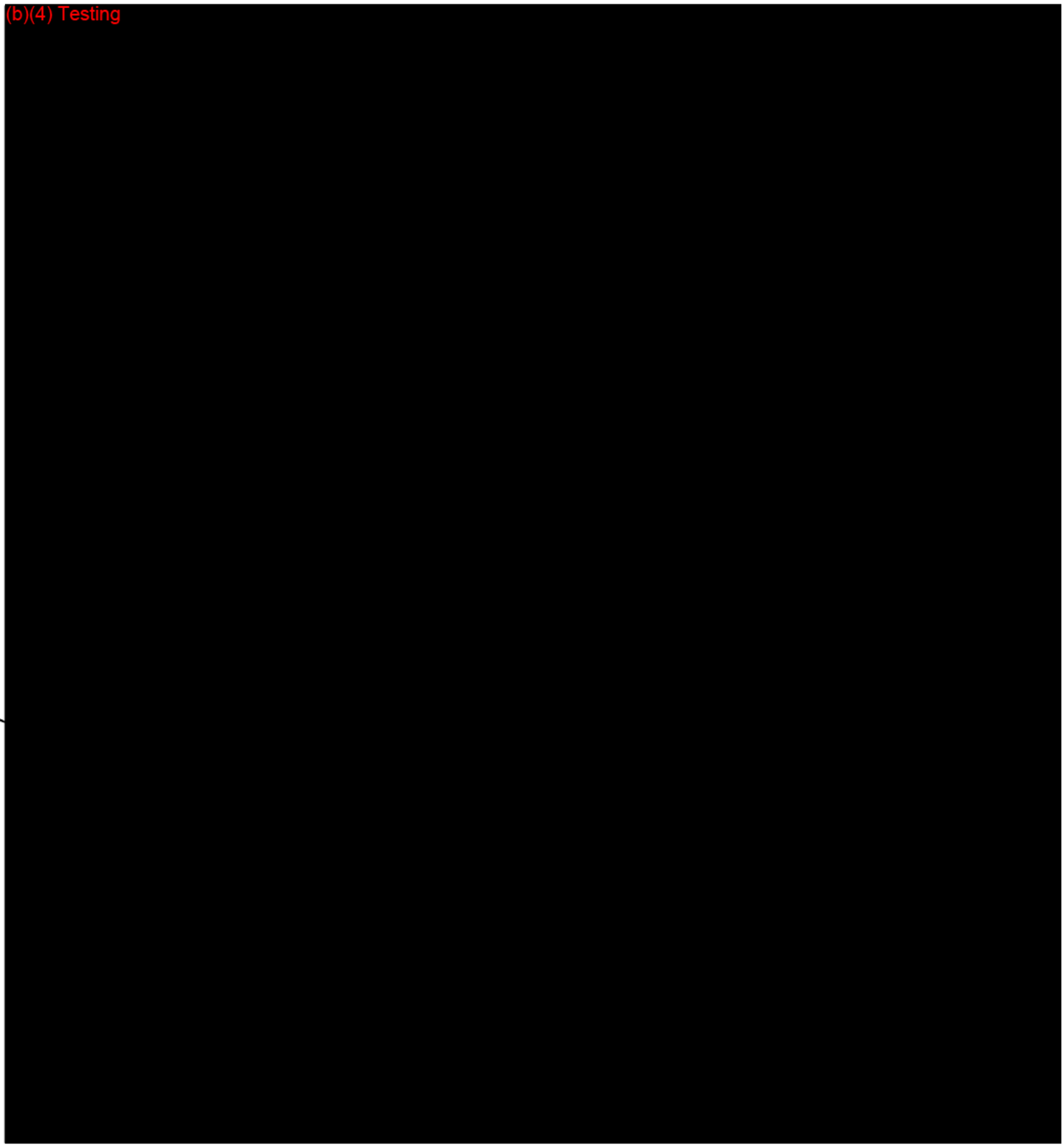

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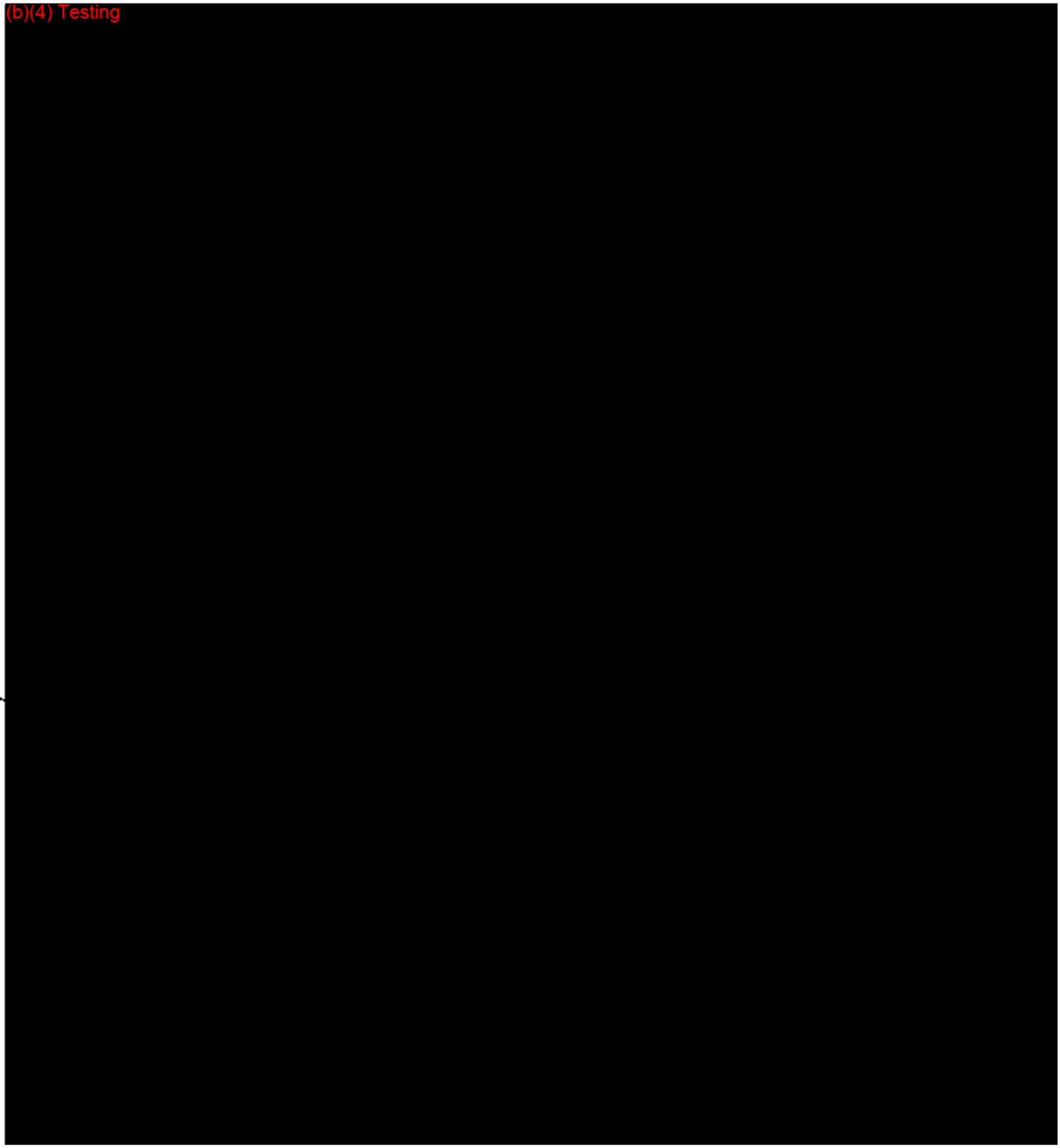

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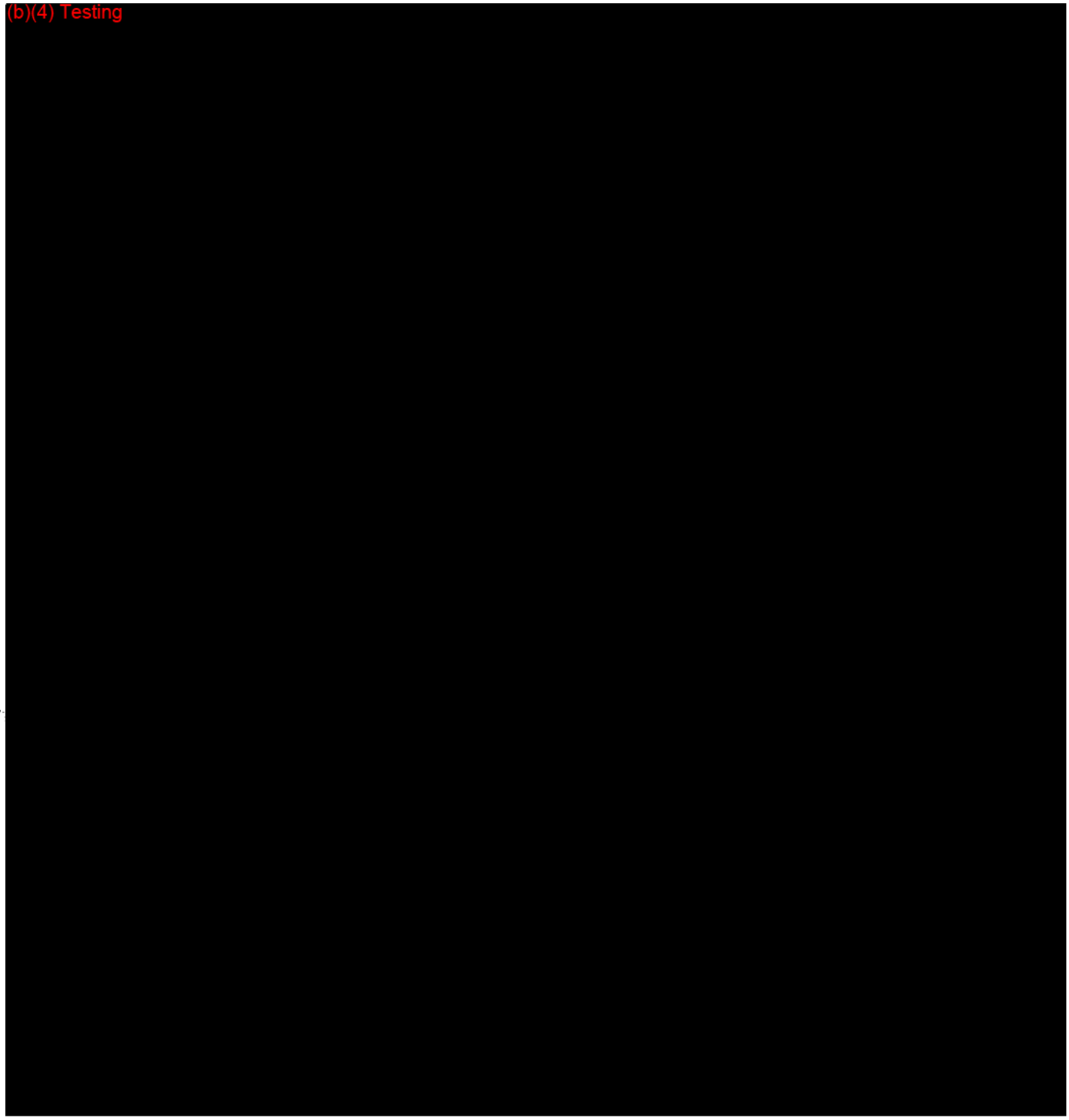

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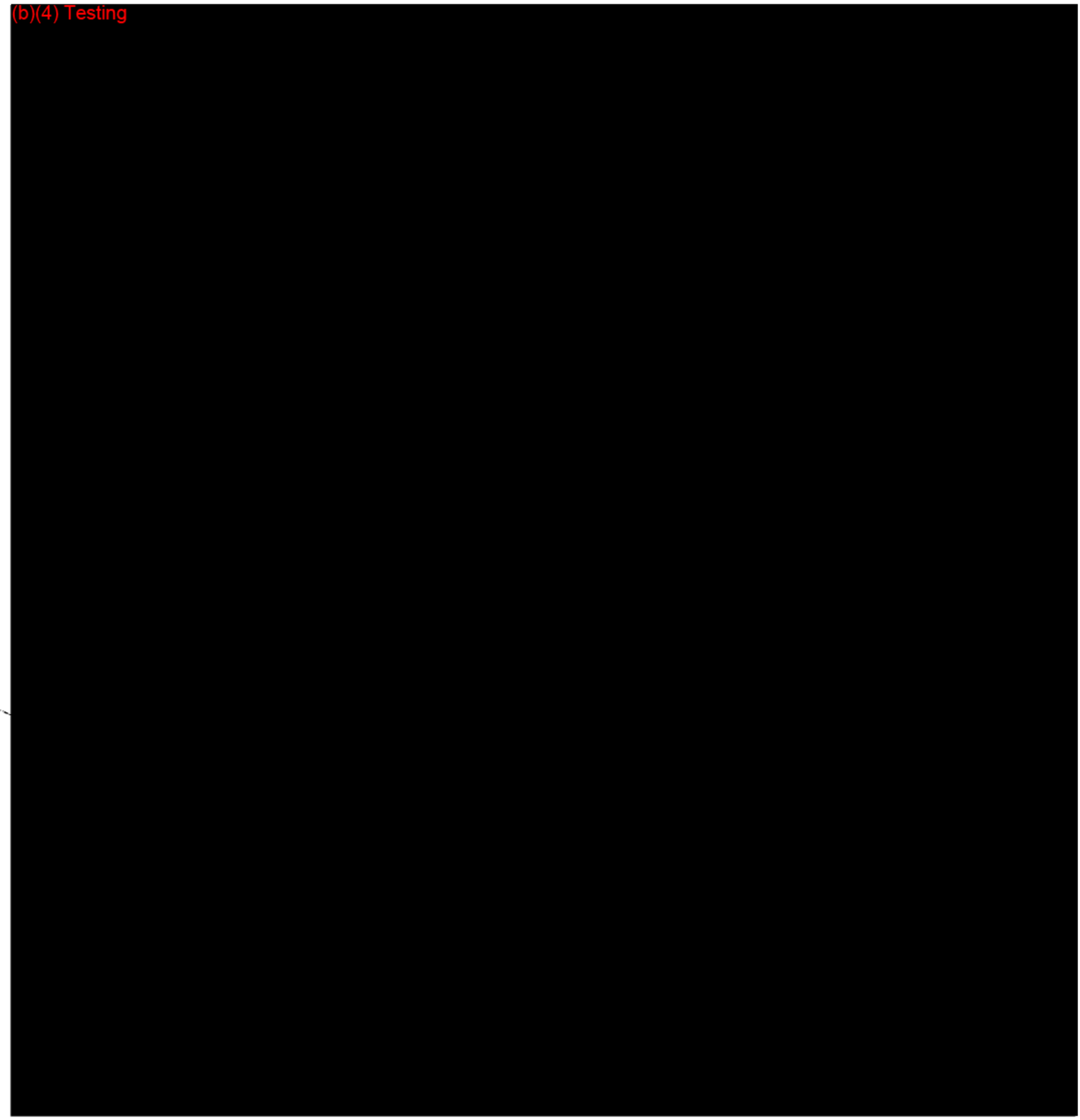

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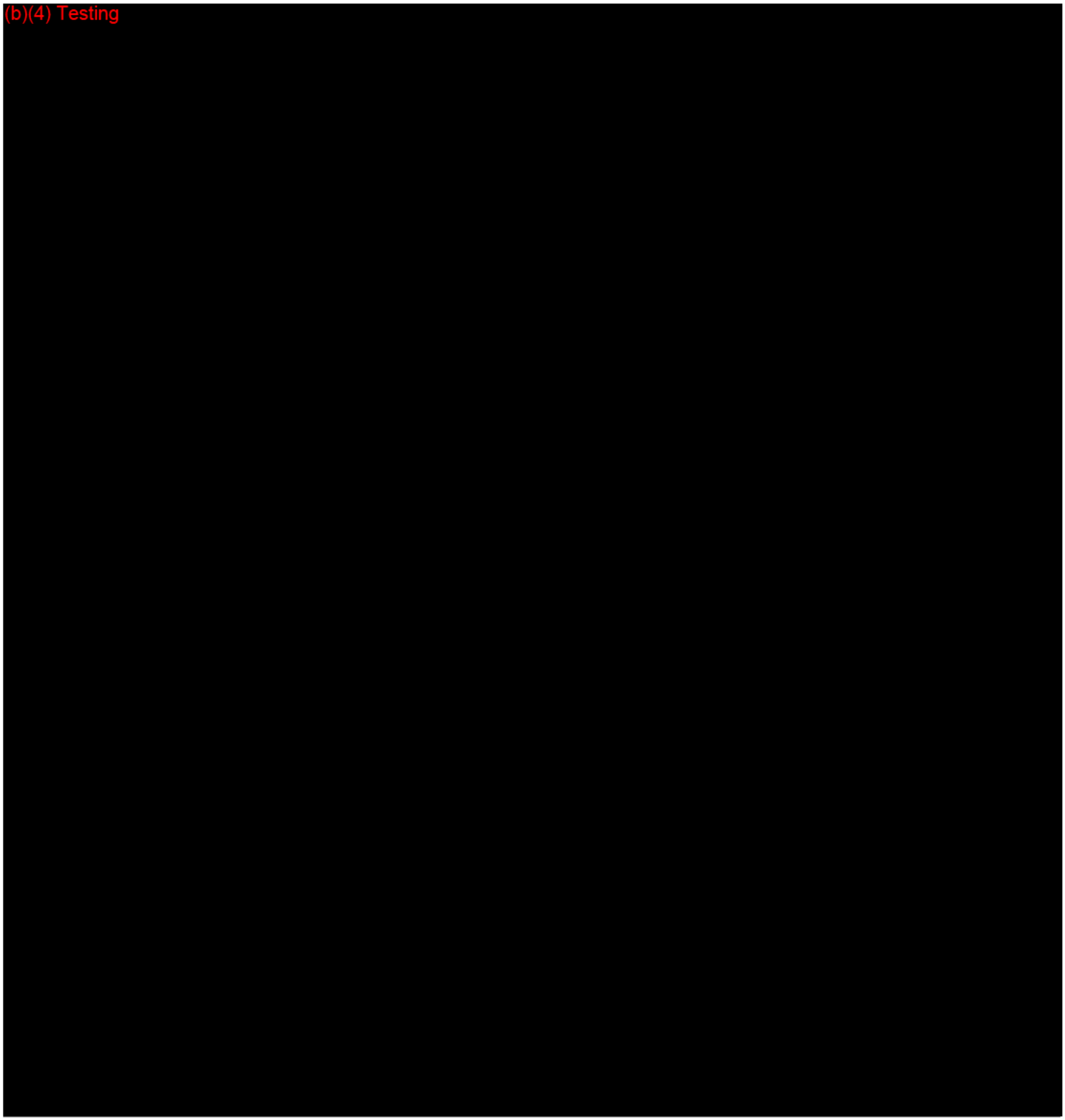

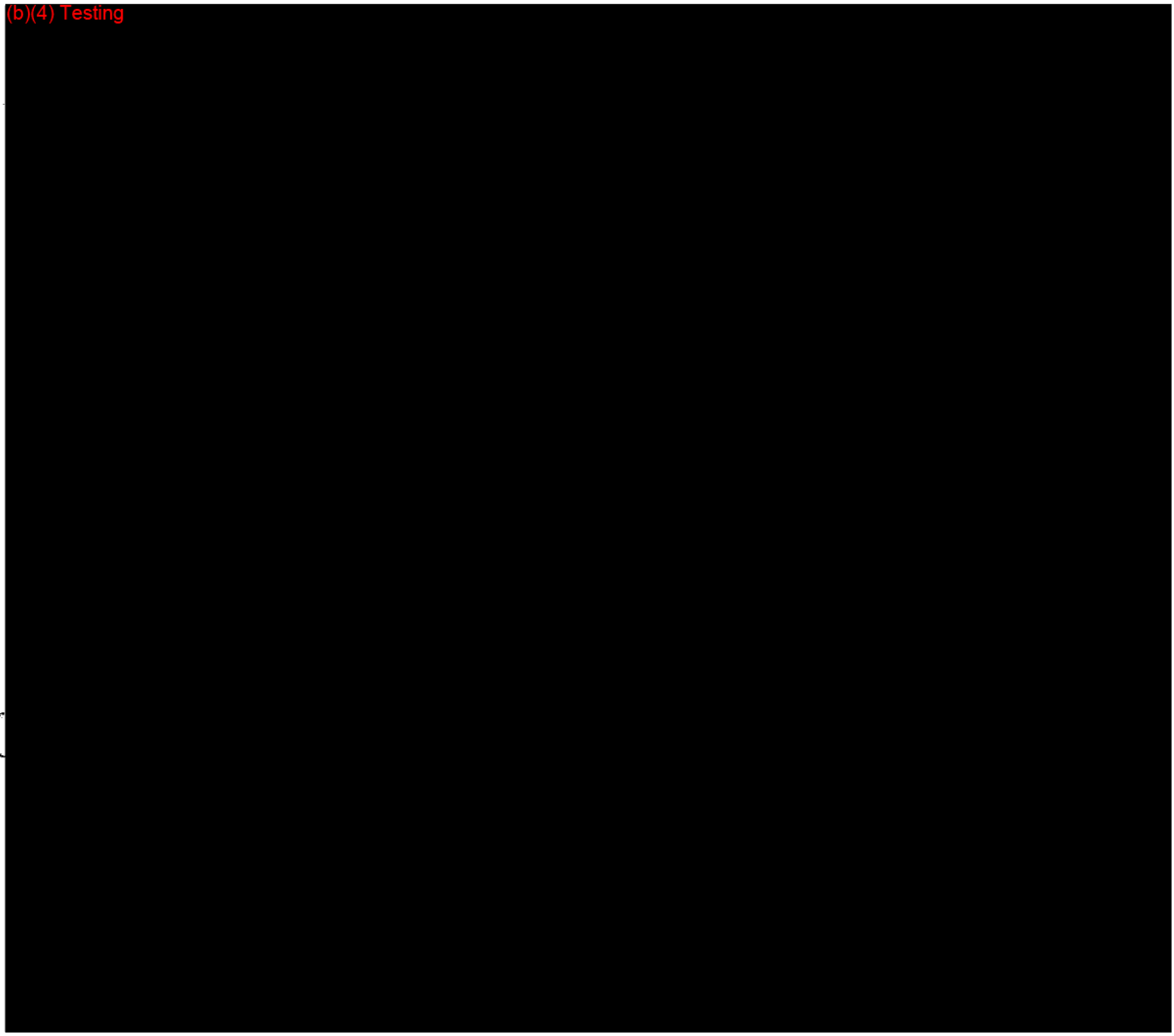

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(b)(4) Testing :
Performance Evaluation

Protocol (b)(4)
Written By: (b)(6)
Date: May 31, 1995

Purpose:

(b)(4)

Procedures:

(b)(4) **Test:**

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(b)(4) **Test:**

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(b)(4) **Tests:**

(b)(4) **Test:**

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[redacted]

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Test:

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(b)(4) Testing

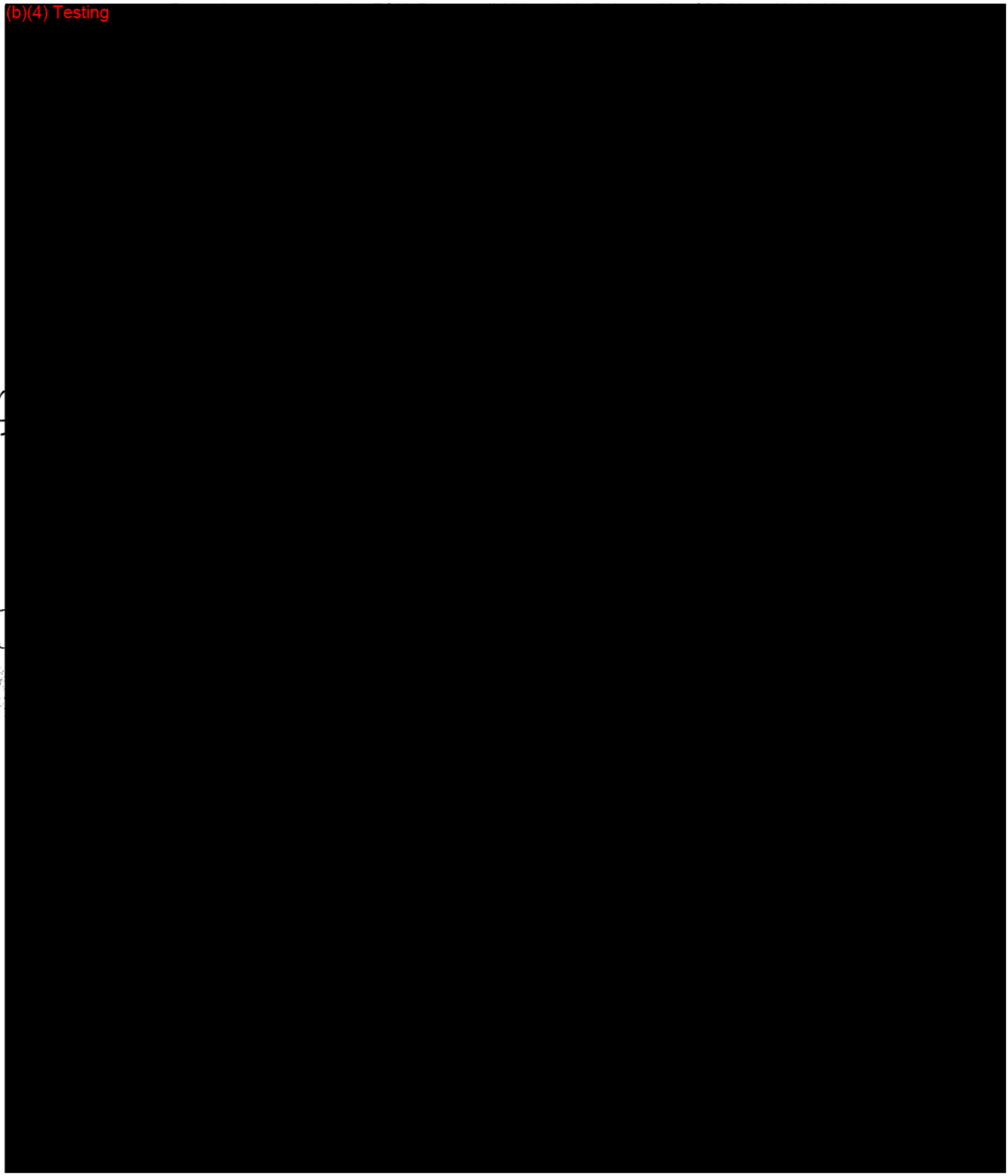

Figure 1

(b)(4) Testing

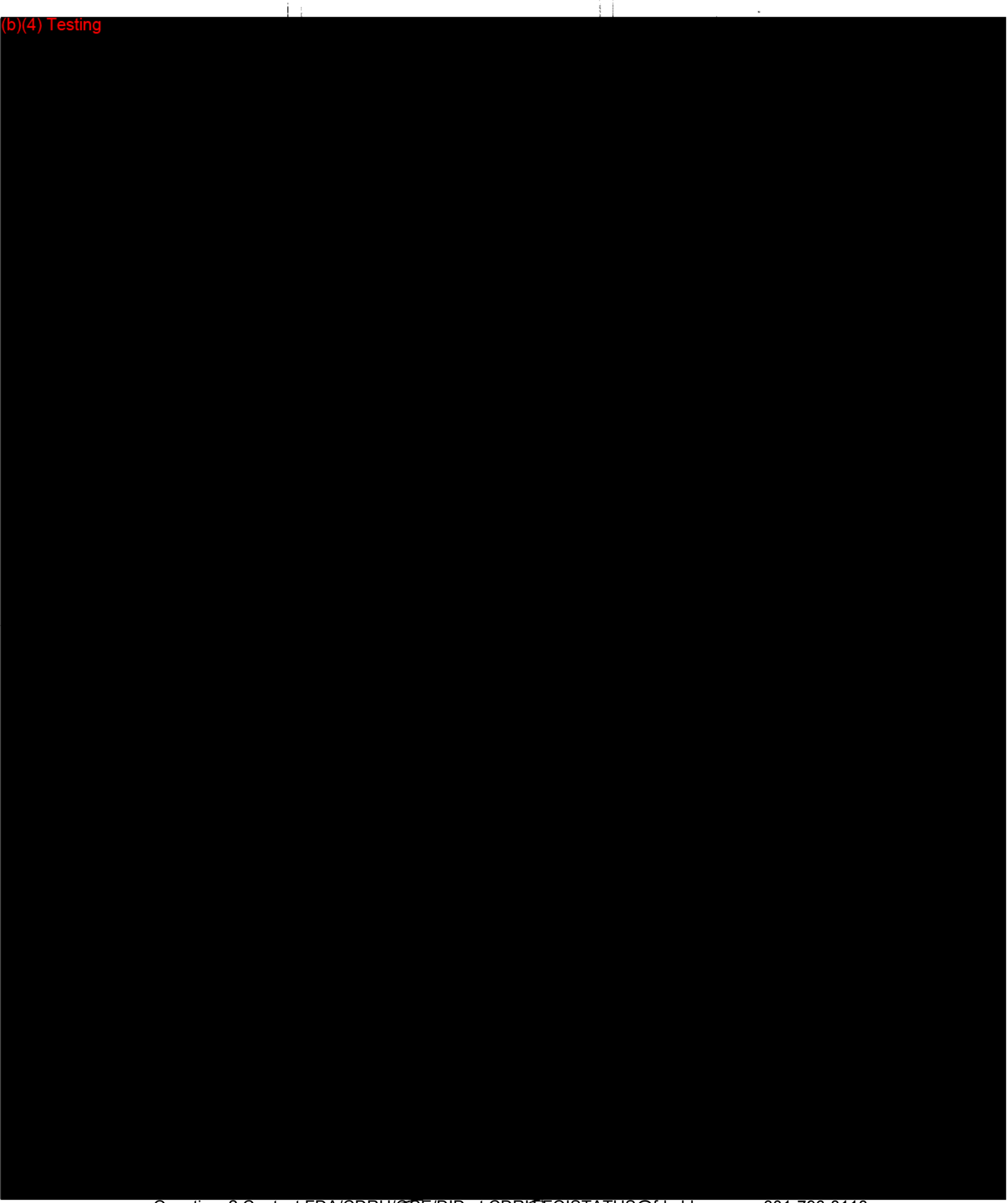

Figure 2

(b)(4) Testing

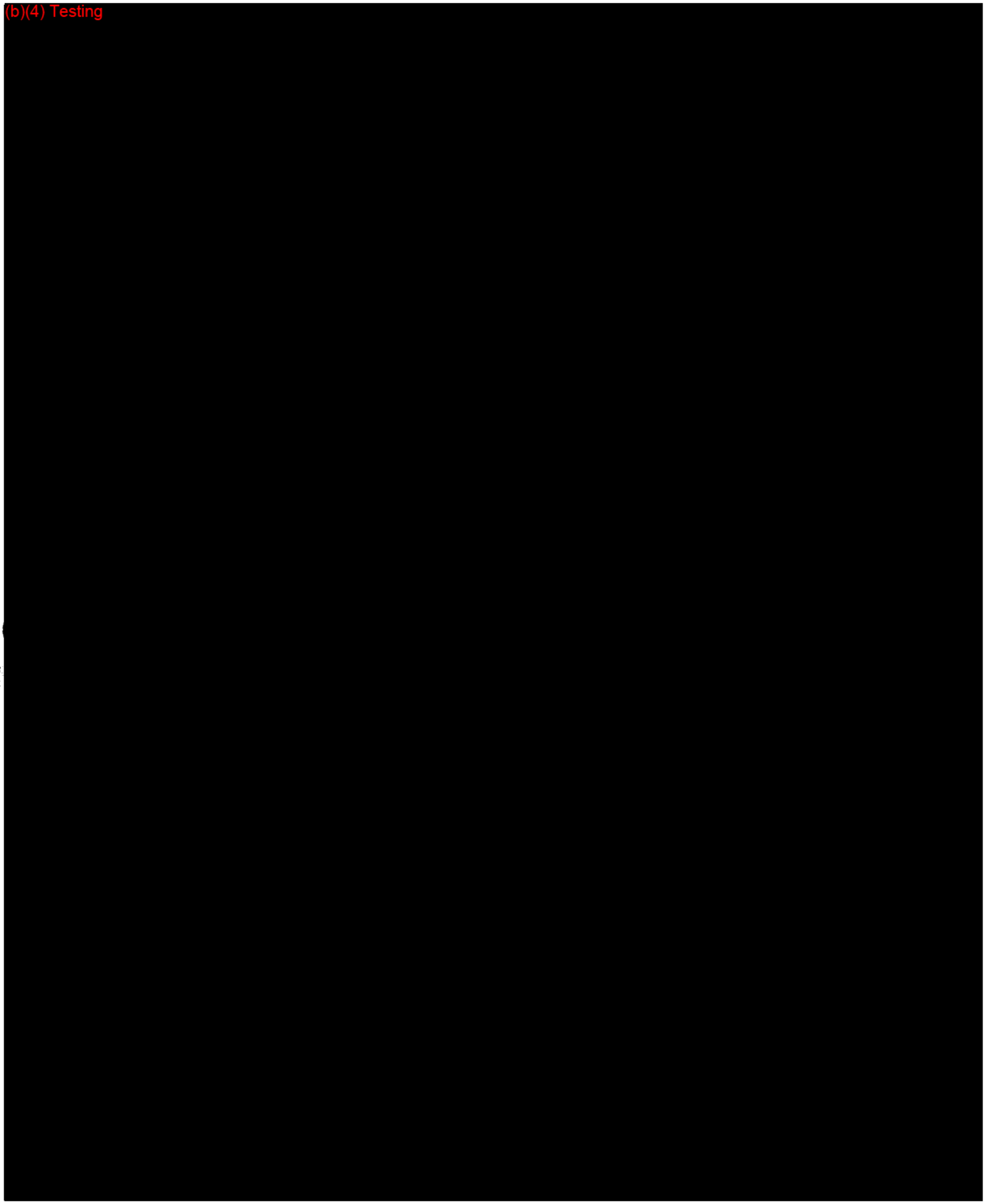

Figure 3

(b)(4) Testing

Figure 4

(b)(4) Testing

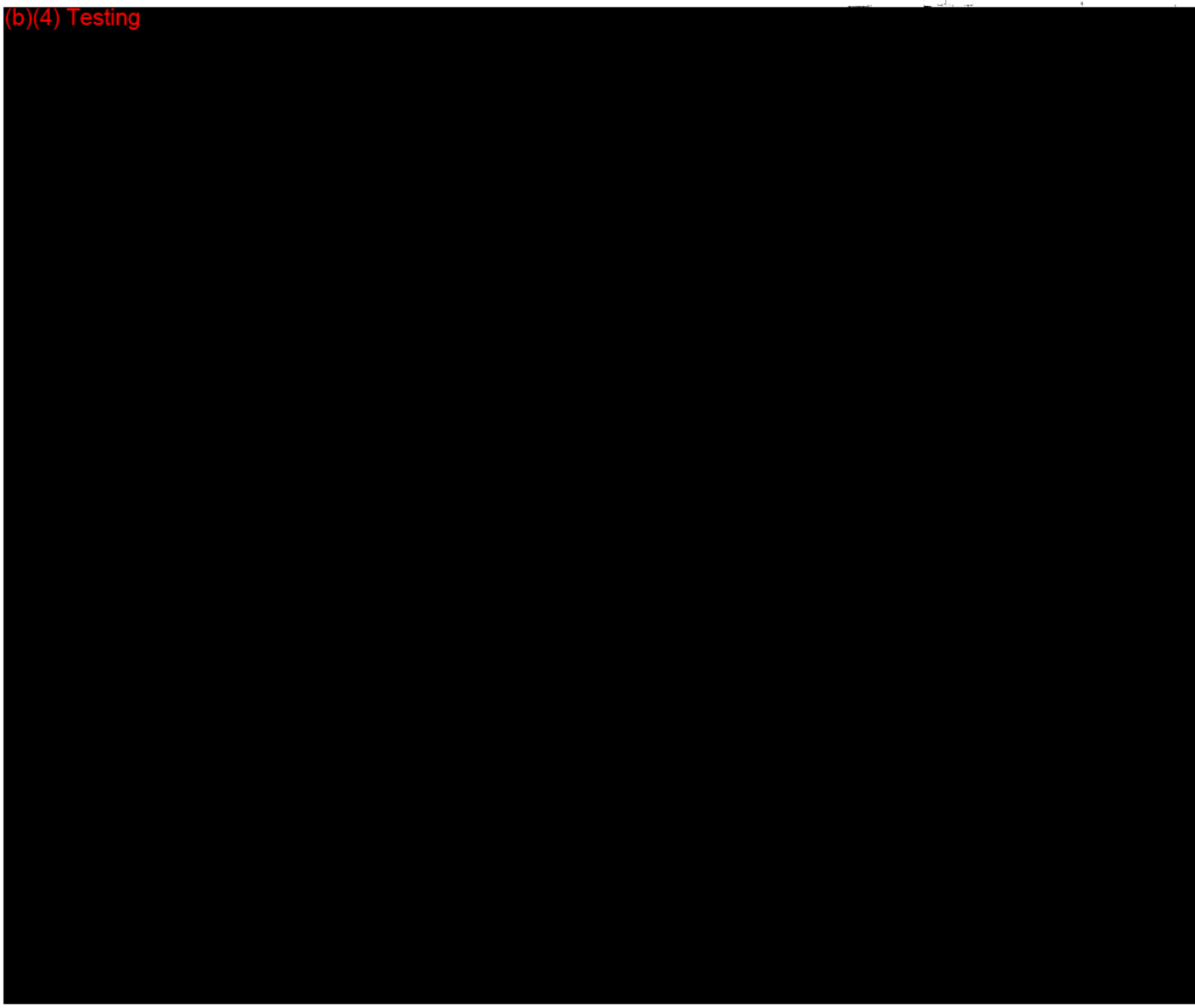

Figure 5