

510(k) Summary

As required by 21 CFR 807.92(c)

OCT 20 2006

510(k) Number: K062251

Date Prepared: August 2, 2006

1. Submitter Information:

Submitter's Name/
Address: St. Jude Medical
14901 DeVeau Place
Minnetonka, MN 55345-2126

Contact Person: Glenn Jacques
Regulatory Affairs Manager
Tel: 952-351-1356
Fax: 952-930-9481
gjacques@sjm.com

2. Device Information:

Trade Name: Reflexion Spiral™ Variable Radius Catheter
Common Name: Catheter, electrode recording
Classification Name: Catheter, electrode recording or probe, electrode recording
Class: Class II, 21 CFR 870.1220, Product Code DRF

3. Predicate Device:

Irvine Biomedical, Inc., (IBI) Inquiry™ Optima™ Steerable Electrophysiology Catheter (K042775)

4. Device Description:

The St. Jude Medical (SJM) Reflexion Spiral™ Variable Radius Catheter (Reflexion Spiral catheter) is a flexible, asymmetric, bi-directional, radiopaque variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates platinum electrodes.

The Reflexion Spiral catheter has a proximal handle (ComfortGrip™) that contains:
1) A shaft actuator mechanism for varying the asymmetrical sweep (90° sweep) and curl (180° curl) of the distal portion of the shaft. 2) A loop actuator mechanism for varying the loop diameter from approximately 25mm to approximately 15mm. 3) An electrical connector fitted into the proximal end of the handle.

5. Indications for Use:

The Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The Reflexion Spiral catheter and the predicate IBI Inquiry™ Optima™ catheter are both intended for electrogram recording and stimulation during electrophysiological studies. The different proximal handles show equivalent performance of the loop radius control and sweep/curl positioning control and does not affect the intended use or the scientific technology of the device.

7. Brief summary of non-clinical tests and results:

The test plan for the Reflexion Spiral catheter was based on FDA Guidance "Electrode Recording Catheter Preliminary Guidance, Draft Version," March 1995 and ISO 10555-1, Sterile Single-Use Intravascular Catheters Part 1: General Requirements. The test results indicate conformance to the standards and reliable performance when used in conformance with the device Instructions for Use. The Reflexion Spiral catheter does not raise any new issues of safety, effectiveness or performance of the device.

8. Statement of Equivalence:

Through the comparison data, the equivalence evaluation, and supporting bench and animal data, SJM considers the Reflexion Spiral™ Variable Radius Catheter to be substantially equivalent to the Irvine Biomedical, Inc. Inquiry™ Optima™ Steerable Electrophysiology Catheter.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

St. Jude Medical
Atrial Fibrillation Division
c/o Mr. Glenn Jacques
Regulatory Affairs Manager
14901 DeVeau Place
Minnetonka MN 55345

OCT 20 2006

Re: K062251

Trade/Device Name: Reflexion Spiral Variable Radius Catheter, Model 402804
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II
Product Code: DRF
Dated: August 2, 2006
Received: August 4, 2006

Dear Mr. Jacques:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

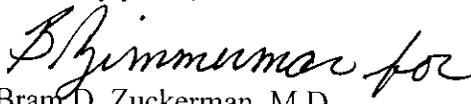
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Glenn Jacques

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K062251

Device Name: Reflexion Spiral™ Variable Radius Catheter

Indications for Use:

The Reflexion Spiral™ catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral™ catheter is to be used to map the atrial regions of the heart.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Bhimmanna
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062251



K062251/A1

October 2, 2006

10/02/2006

10/02/2006 10:26

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

K-22

**RE: Traditional 510(k) Amendment for K062251
Reflexion Spiral™ Variable Radius Catheter
Submission of Spiral 1 year Accelerated Aging Report #90001017**

Dear Sir/Madam:

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR Part 807.81, Subpart E, St. Jude Medical is submitting the attached amendment to the Reflexion Spiral traditional 510(k), K062251 previously received by the FDA on August 4, 2006. This submission was prepared using the CDRH Guidance for Industry and FDA Staff entitled "Format for Traditional and Abbreviated 510(k)'s" that was issued August 12, 2005. This amendment is adding the Spiral 1 year Accelerated Aging Report #90001017 to the original submission for this new device.

The 510(k) notification requests clearance for the Reflexion Spiral™ Variable Radius Catheter, which is a flexible, asymmetrical, bi-directional, variable radius loop electrophysiology catheter.

As per a previous FDA reviewer, SJM would like to request a copy of all correspondence regarding this submission be sent to the facsimile number listed below.

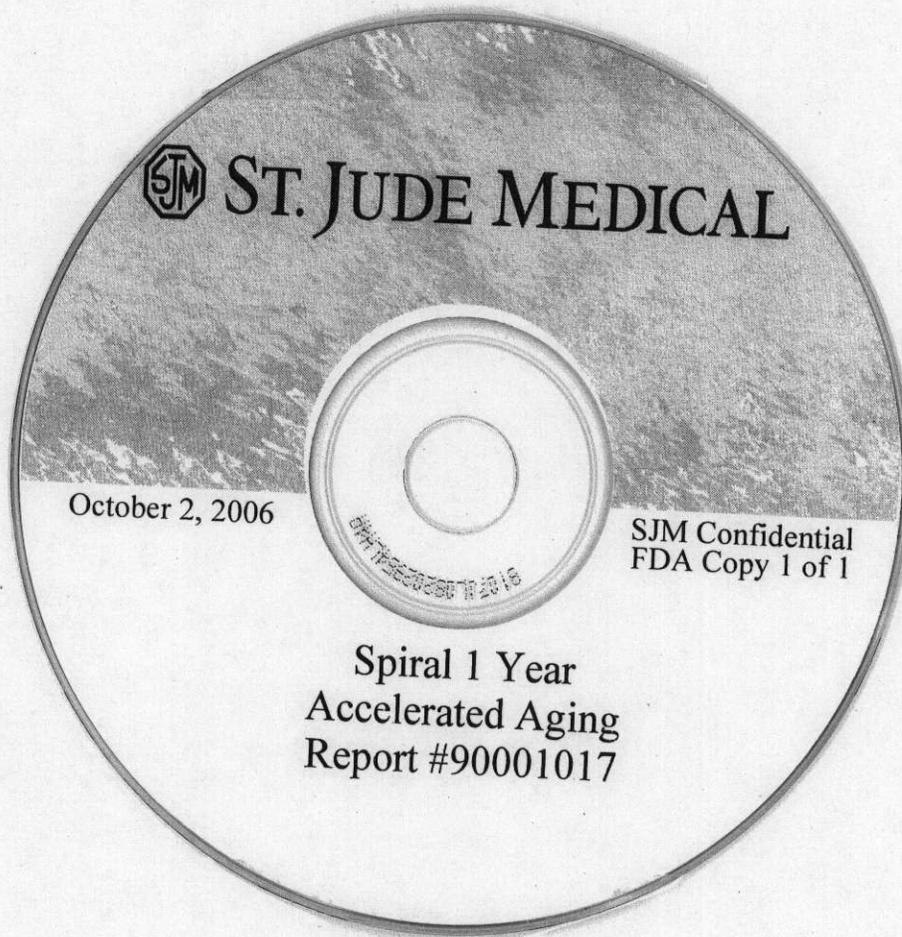
Primary Contact

Glenn Jacques
Regulatory Affairs Manager
Tel: 952-351-1356
Fax: 952-930-9481
gjacques@sjm.com

Alternative Contact:

Mac McKeen
Regulatory Affairs Director
Tel: 952-351-1544
Fax: 952-930-9481
mmckeen@sjm.com

ST. JUDE MEDICAL
14901 DEVEAU PLACE • MINNETONKA, MN • 55345
PHONE: (952) 933-4465 • FAX: (952) 930-9481



CDs Received

WITS Entry

1 CD with entire submission 1CDT

CDs with entire submission XCDT

1 CD with each copy of submission 1CDPC

CDs with each copy of submission XCDPC

Check here if CDs were bound into volume(s)	<input type="checkbox"/>	<u>X</u> CDTB – <u>X</u> CDPCB
Letter Stated CD(s) – NO CDs found in Packaging	<input type="checkbox"/>	LSCD – NO CDs
True Electronic Submission (E-Copy) – w/proper cover letter stating so	<input type="checkbox"/>	ESUB 1/X – 1 or X

Filename: C:\My Documents\Word\Forms\CDs Received in Mailroom



This submission contains trade secret and confidential commercial information that should be protected in accordance with 21 CFR 807.95.

If additional information is required, please contact the undersigned by FAX.

Sincerely,

A handwritten signature in black ink, appearing to read 'Glenn Jacques', written in a cursive style.

Glenn Jacques
Regulatory Affairs Manager

Enclosures
Spiral 1 year Accelerated Aging Report #90001017

ST. JUDE MEDICAL
14901 DEVEAU PLACE • MINNETONKA, MN • 55345
PHONE: (952) 933-4465 • FAX: (952) 930-9481

(b)(4) Confidential and Proprietary Information

Aging Report

Version 1

Page 1 of 75

 ST. JUDE MEDICAL

REPORT

No. (b)(4) Confidential and Proprietary
Project No. (b)(4) Confidential and Proprietary
Date: September 27, 2006
Version: 1
Page 1 of 75

(b)(4) Confidential and Proprietary Information - Testing

Report Approvals

(b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 2006

St. Jude Medical
Atrial Fibrillation Division
c/o Mr. Glenn Jacques
Regulatory Affairs Manager
14901 DeVeau Place
Minnetonka MN 55345

Re: K062251

Trade/Device Name: Reflexion Spiral Variable Radius Catheter, Model 402804
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II
Product Code: DRF
Dated: August 2, 2006
Received: August 4, 2006

Dear Mr. Jacques:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). 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.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Glenn Jacques

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K062251

Device Name: Reflexion Spiral™ Variable Radius Catheter

Indications for Use:

The Reflexion Spiral™ catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral™ catheter is to be used to map the atrial regions of the heart.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Bhimmaram
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062251

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

August 04, 2006

ST. JUDE MEDICAL
14901 DEVEAU PL.
MINNETONKA, MN 55345
ATTN: GLENN JACQUES

510(k) Number: K062251
Received: 03-AUG-2006
Product: REFLEXION SPIRAL
VARIABLE RADIUS
CATHETER, MODEL
402804

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (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 510(k) submission.

Please note the following documents as they relate to 510(k) review:
1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).
3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsup.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

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

K062257



**Reflexion Spiral™
Variable Radius Catheter**

TRADITIONAL 510(k)

Submitted by:

**St. Jude Medical
14901 DeVeau Place
Minnetonka, MN 55345-2126**

Establishment Registration Number: (b) (4)

August 2, 2006

101

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Appendix C	Reflexion Spiral Variable Radius Catheter Draft Labeling <ul style="list-style-type: none">• Instructions for Use• Tray Label• Box Label
Appendix D	Risk Analysis for Reflexion Spiral Steerable Diagnostic Catheter
Appendix E	Reflexion Spiral Duo-Decapolar Design Verification Testing Report
Appendix F	(b)(4) Confidential and Proprietary Information - Testing
Appendix G	Biocompatibility Testing of the Reflexion Spiral EP Diagnostic Catheter
Appendix H	Preclinical evaluation of the Reflexion Spiral™ duo-decapolar diagnostic catheter, RO (b)(4)

Reflexion Spiral™ Variable Radius Mapping Catheter
Traditional 510(k)
St. Jude Medical, August 2006 **Confidential**

Section 1

Medical Device User Fee Cover Sheet

MEDICAL DEVICE USER FEE COVER SHEET

The Medical Device User Fee Cover Sheet is provided on the following page.

Reflexion Spiral™ Variable Radius Catheter
Traditional 510(k)
St. Jude Medical, August 2006

Page 1

Form Approved OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
---	--

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

<p>1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)</p> <p>ST JUDE MEDICAL DAIG DIVISION INC 14901 DEVEAU PLACE MINNETONKA MN 55345 US</p> <p>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)</p>	<p>2. CONTACT NAME Elsa Linke</p> <p>2.1 E-MAIL ADDRESS elinke@sjm.com</p> <p>2.2 TELEPHONE NUMBER (include Area code) 952-351-1527</p> <p>2.3 FACSIMILE (FAX) NUMBER (Include Area code) 952-930-9481</p>
---	--

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/dc/mdufma>)

<p>Select an application type:</p> <p><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</p> <p><input type="checkbox"/> Biologics License Application (BLA)</p> <p><input type="checkbox"/> Premarket Approval Application (PMA)</p> <p><input type="checkbox"/> Modular PMA</p> <p><input type="checkbox"/> Product Development Protocol (PDP)</p> <p><input type="checkbox"/> Premarket Report (PMR)</p>	<p>3.1 Select one of the types below</p> <p><input checked="" type="checkbox"/> Original Application</p> <p>Supplement Types:</p> <p><input type="checkbox"/> Efficacy (BLA)</p> <p><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</p> <p><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</p> <p><input type="checkbox"/> 180-day (PMA, PMR, PDP)</p>
---	--

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b) (4)

24-Jul-2006

Form FDA 3601 (08/2003)

(Close Window)

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Section 2

CDRH Premarket Review Submission Cover Sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

The CDRH Premarket Review Submission Cover Sheet is provided on the following page.

Reflexion Spiral™ Variable Radius Catheter
Traditional 510(k)
St. Jude Medical, August 2006

Page 2

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission August 2, 2006	User Fee Payment ID Number (b)(4) Confidential	FDA Submission Document Number (if known) Not Applicable
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SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name St. Jude Medical	Establishment Registration Number (if known) 2182269		
Division Name (if applicable) Atrial Fibrillation Division	Phone Number (including area code) (952) 933-4700		
Street Address 14901 DeVeau Place	FAX Number (including area code) (952) 930-9481		
City Minnetonka	State / Province MN	ZIP/Postal Code 55345	Country USA
Contact Name Glenn Jacques			
Contact Title Regulatory Affairs Manager		Contact E-mail Address gjacques@sjm.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final			
<input type="checkbox"/> Other Reason (specify):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DRF		3		4
5		6	7		8

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K042775	1	Inquiry™ Optima™ Steerable Electrophysiology Catheter	1	Irvine Biomedical, Inc.
2	P960016 Supplement 14	2	Safire Ablation Catheter (reference predicate)	2	St. Jude Medical
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Steerable Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Reflexion Spiral™ Variable Radius Catheter	1	402804
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
N/A					
7	8	9	10	11	12

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G

PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code DRF	C.F.R. Section (if applicable) 21 CFR 870.1220	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Cardiovascular		

Indications (from labeling)

The Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

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

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 2182269		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name St. Jude Medical			Establishment Registration Number (b) (4)		
Division Name (if applicable) Atrial Fibrillation Division			Phone Number (including area code) (952) 933-4700		
Street Address 14901 DeVeau Place			FAX Number (including area code) (952) 930-9481		
City Minnetonka		State / Province MN	ZIP/Postal Code 55345	Country USA	
Contact Name Glenn Jacques		Contact Title Regulatory Affairs Manager		Contact E-mail Address gjacques@sjm.com	

(b)(4) Confidential and Proprietary Information

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	13485	ISO	Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001	2003	7/1/03
2	10993-1	ISO	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing	2003	8/3/2003
3	550	EN	Sterilization of Medical Devices – Validation and Routine Control of EtO Sterilization	1994	11/1/94
4	556-1	EN	Sterilization of Medical Devices – Requirements for medical devices to be designated "STERILE": Part 1- Requirements for Terminally Sterilized medical devices	2001	12/11/2001
5	10555-1	ISO	Sterile, single-use intravascular catheters Amendment 1 Amendment 2	1995 1999 2004	6/15/1995 7/1/1999 5/1/2004
6	11135	ISO	Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization	1994	2/1/1994
7	11138: Part 2	ISO	Sterilization of health care products- Part 2: Biological indicators for ethylene oxide sterilization.	1994	10/1/1994

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
8	11737	AAMI	Sterilization of medical devices-Microbiological methods	1995	12/1/1995
9	14161	ISO	Sterilization of health care products-Biological indicators-Guidance for the selection, use and interpretation of results	2000	10/1/2000
10	11607	AAMI	Packaging for Terminally Sterilized Medical Devices	2003	2/1/2003
11	14644 Part 1 -2	ISO	Cleanrooms and associated controlled environment Part 1: Classification of air cleanliness Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	1999 2000	5/1/1999 9/15/2000
12	F1980-99	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	99	11/1/1999
13	F640-79	ASTM	Standard Test Method for Radiopacity of Plastics for Medical Use	2000	1/1/2000
14	14971	ISO	Medical devices - Application of risk management to medical devices, First Edition. Amendment 1	2003	3/1/2003
15					

Section 3

510(k) Cover Letter

510(k) COVER LETTER

The 510(k) Cover Letter is provided on the following page.

Reflexion Spiral™ Variable Radius Catheter
Traditional 510(k)
St. Jude Medical, August 2006

Page 3



ST. JUDE MEDICAL

August 2, 2006

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

RECEIVED
2006 AUG -3 A 11:39
FDA/CDRH/OCE/DID

RE: Traditional 510(k) Notification (21 CFR 807.90(e))
Reflexion Spiral™ Variable Radius Catheter
Common Name: Catheter, electrode recording or probe, electrode recording
Classification Regulation: 870.1220
Class: II
Panel: Cardiovascular
Product Code: DRF

Dear Sir/Madam:

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR Part 807, Subpart E, St. Jude Medical is submitting the attached traditional 510(k) notification. This submission was prepared using the CDRH Guidance for Industry and FDA Staff entitled "Format for Traditional and Abbreviated 510(k)'s" that was issued August 12, 2005. The basis for this submission is a new device.

This 510(k) notification requests clearance for the Reflexion Spiral™ Variable Radius Catheter, which is a flexible, asymmetrical, bi-directional, variable radius loop electrophysiology catheter.

As per a previous FDA reviewer, SJM would like to request a copy of all correspondence regarding this submission be sent to the facsimile number listed below.

Primary Contact
Glenn Jacques
Regulatory Affairs Manager
Tel: 952-351-1356
Fax: 952-930-9481
gjacques@sjm.com

Alternative Contact:
Mac McKeen
Regulatory Affairs Director
Tel: 952-351-1544
Fax: 952-930-9481
mmckeen@sjm.com

ST. JUDE MEDICAL
14901 DEVEAU PLACE • MINNETONKA, MN • 55345
PHONE: (952) 933-4465 • FAX: (952) 930-9481

K19 114



ST. JUDE MEDICAL

For principal factors about the design and use of the Reflexion Spiral™ Catheter, refer to **Table 1**.

Table 1: Principal Factors about the design and use of the Reflexion Spiral Catheter

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This submission contains trade secret and confidential commercial information that should be protected in accordance with 21 CFR 807.95.

If additional information is required, please contact the undersigned by FAX.

Sincerely,

Glenn Jacques
Regulatory Affairs Manager

Enclosures

ST. JUDE MEDICAL
14901 DEVEAU PLACE • MINNETONKA, MN • 55345
PHONE: (952) 933-4465 • FAX: (952) 930-9481

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Section 4

Indications for Use Statement

INDICATIONS FOR USE STATEMENT

The Indications for Use Statement is provided on the following page.

Reflexion Spiral™ Variable Radius Catheter
Traditional 510(k)
St. Jude Medical, August 2006

Page 4

INDICATIONS FOR USE

510(K) Number (if known): K062251

Device Name: Reflexion Spiral™ Variable Radius Catheter

Indications for Use:

The Reflexion Spiral™ catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral™ catheter is to be used to map the atrial regions of the heart.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

510(k) SUMMARY

The 510(k) Summary is provided on the following page.

510(k) Summary

As required by 21 CFR 807.92(c)

510(k) Number: K062251

Date Prepared: August 2, 2006

1. Submitter Information:

Submitter's Name/
Address: St. Jude Medical
14901 DeVeau Place
Minnetonka, MN 55345-2126

Contact Person: Glenn Jacques
Regulatory Affairs Manager
Tel: 952-351-1356
Fax: 952-930-9481
gjacques@sjm.com

2. Device Information:

Trade Name: Reflexion Spiral™ Variable Radius Catheter
Common Name: Catheter, electrode recording
Classification Name: Catheter, electrode recording or probe, electrode recording
Class: Class II, 21 CFR 870.1220, Product Code DRF

3. Predicate Device:

Irvine Biomedical, Inc., (IBI) Inquiry™ Optima™ Steerable Electrophysiology Catheter (K042775)

4. Device Description:

The St. Jude Medical (SJM) Reflexion Spiral™ Variable Radius Catheter (Reflexion Spiral catheter) is a flexible, asymmetric, bi-directional, radiopaque variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates platinum electrodes.

The Reflexion Spiral catheter has a proximal handle (ComfortGrip™) that contains:
1) A shaft actuator mechanism for varying the asymmetrical sweep (90° sweep) and curl (180° curl) of the distal portion of the shaft. 2) A loop actuator mechanism for varying the loop diameter from approximately 25mm to approximately 15mm. 3) An electrical connector fitted into the proximal end of the handle.

5. Indications for Use:

The Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The Reflexion Spiral catheter and the predicate IBI Inquiry™ Optima™ catheter are both intended for electrogram recording and stimulation during electrophysiological studies. The different proximal handles show equivalent performance of the loop radius control and sweep/curl positioning control and does not affect the intended use or the scientific technology of the device.

7. Brief summary of non-clinical tests and results:

The test plan for the Reflexion Spiral catheter was based on FDA Guidance “Electrode Recording Catheter Preliminary Guidance, Draft Version,” March 1995 and ISO 10555-1, Sterile Single-Use Intravascular Catheters Part 1: General Requirements. The test results indicate conformance to the standards and reliable performance when used in conformance with the device Instructions for Use. The Reflexion Spiral catheter does not raise any new issues of safety, effectiveness or performance of the device.

8. Statement of Equivalence:

Through the comparison data, the equivalence evaluation, and supporting bench and animal data, SJM considers the Reflexion Spiral™ Variable Radius Catheter to be substantially equivalent to the Irvine Biomedical, Inc. Inquiry™ Optima™ Steerable Electrophysiology Catheter.

Section 6

Truthful and Accuracy Statement

TRUTHFUL AND ACCURACY STATEMENT

The Truthful and Accuracy Statement is provided on the following page.

Reflexion Spiral™ Variable Radius Catheter
Traditional 510(k)
St. Jude Medical, August 2006

Page 6

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR 807.87(k)]**

I certify that, in my capacity as Regulatory Affairs Manager for St. Jude Medical, 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

Glenn Jacques
Typed Name

Dated: August 2, 2006

Premarket Notification [510(k)] Number

Section 7

Class III Summary and Certification

CLASS III SUMMARY AND CERTIFICATION

This section does not apply.

The Reflexion Spiral™ Variable Radius Catheter is a Class II device.

Classification registration: 870.1220

Product Code: DRF

Section 8 **Financial Certification or Disclosure Statement**

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply.

The Reflexion Spiral™ Variable Radius Catheter is a Class II device.

Section 9**Declarations of Conformity****DECLARATIONS OF CONFORMITY**

The following voluntary standards have been referenced in this Reflexion Spiral Variable Radius Catheter 510(k) submission. Refer to **Table 9.1**.

Table 9.1 – Voluntary Standards

Quality System	<ul style="list-style-type: none"> • ISO 13485, Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001 • ISO 14971, Medical devices -- Application of risk management to medical devices
Biocompatibility	<ul style="list-style-type: none"> • ISO 10993-01: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
Sterilization and Pyrogenicity	<ul style="list-style-type: none"> • EN 550: Sterilization of Medical Devices – Validation and Routine Control of EtO Sterilization • EN 556: Sterilization of Medical Devices – Requirements for medical devices to be designated “STERILE” • ISO 10555: Sterile, single-use intravascular catheters • ISO 11135: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization • ISO 11138: Sterilization of health care products-Part 2:Biological indicators for ethylene oxide sterilization • ISO 11737: Sterilization of medical devices-Microbiological methods • ISO 14161: Sterilization of health care products-Biological indicators-Guidance for the selection, use and interpretation of results • FDA Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices, 1987.
Packaging	<ul style="list-style-type: none"> • ISO 11607, Packaging for Terminally Sterilized Medical Devices • ASTM F 1980-99, Standard Guide for Accelerated Aging of Sterile Medical Device Packages • ASTM D4169-05a, Simulated Distribution Testing
Product Specific	<ul style="list-style-type: none"> • ISO 10555-1, Sterile, Single-Use Intravascular Catheters Part 1: General Requirements • ASTM F640-79: Standard Test Methods for Radiopacity of Plastics for Medical Use

EXECUTIVE SUMMARY

Introduction

This 510k application is being submitted to obtain market clearance of the St. Jude Medical Reflexion Spiral™ Variable Radius Catheter. The predicate device referenced for this submission is the Inquiry Optimal catheter marketed by Irvine Biomedical Inc, a St. Jude Medical company, and cleared under K042775. This submission contains a summary of the design testing and process controls employed in the development and manufacture of this product. This product was designed, developed, tested, and manufactured in accordance with applicable St. Jude Medical procedures.

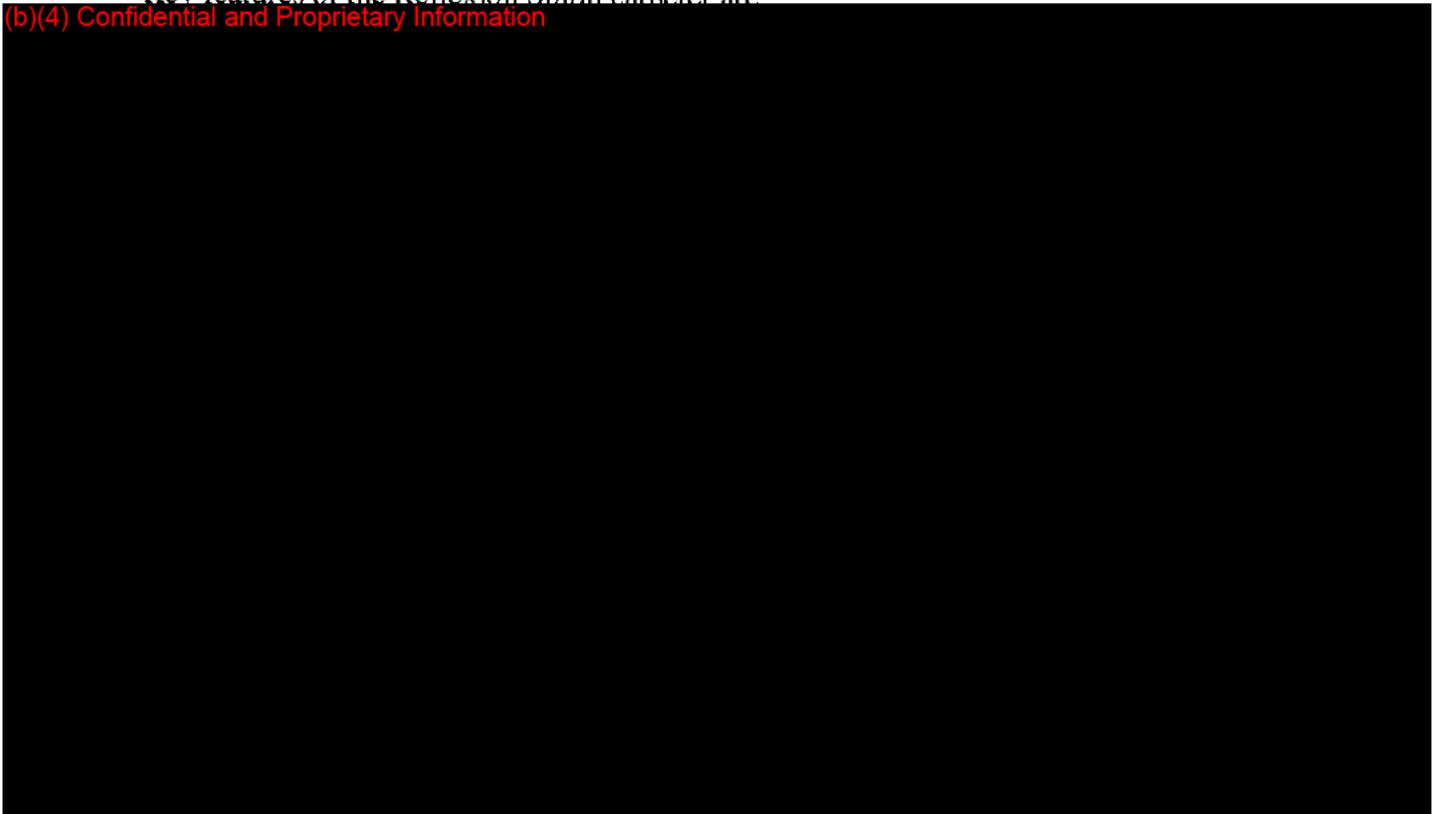
Product Description

The St Jude Medical (SJM) Reflexion Spiral™ Variable Radius Catheter (Reflexion Spiral catheter) is a flexible, asymmetric, bidirectional, variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates 20 platinum electrodes.

The Reflexion Spiral catheter has a proximal handle (ComfortGrip™) that contains: 1) A shaft actuator mechanism for varying the asymmetrical sweep (90° sweep) and curl (180° curl) of the distal portion of the shaft. 2) A loop actuator mechanism for varying the loop diameter from approximately 25mm to approximately 15mm. 3) An electrical connector fitted into the proximal end of the handle.

Key features of the Reflexion Spiral catheter are:

(b)(4) Confidential and Proprietary Information



Section 10

Executive Summary

Indications for Use

The Reflexion Spiral™ catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral™ catheter is to be used to map the atrial regions of the heart.

The above indication for use statement is equivalent to the predicate Indication for Use statement of the Inquiry™ Optima™ Electrophysiology Catheter (Inquiry Optima catheter) marketed by Irvine Biomedical Inc, a St. Jude Medical company, and cleared under K042775.

Device Comparison

The predicate device referenced for this submission is the Inquiry Optima catheter marketed by Irvine Biomedical Inc, a St. Jude Medical company, and cleared under K042775.

Predicate Device Description:

Irvine Biomedical Inc. Inquiry™ Optima™ Steerable Electrophysiology Catheter

510(k) Number: K042775

Clearance Date: Nov 4, 2004

Brief Description: The Inquiry Optima catheter is a flexible, radiopaque catheter with a variable number of electrodes with the first electrode located at the distal tip and the other band electrodes following at predetermined distances. A connecting cable is used to connect the catheter to electrogram devices. The catheter has a distal loop in a plane perpendicular to the catheter body. The circumferential shape or loop allows the electrophysiologist to record the potentials of cardiac structures without changing the position of the catheter. The catheter shaft and/or loop is steerable by manipulating the handle. The placement of the electrodes around the entire circumference of the distal loop also assists the electrophysiologist during fluoroscopy with visualization. The distal loop shape is easily straightened with the thumb and forefinger to facilitate insertion into sheaths and introducers. Once the catheter is extended beyond the sheath, the catheter resumes its pre-formed shape. The device is supplied sterile and is intended for single use only.

Table 10.1 provides a comparison of device characteristics between the proposed Reflexion Spiral catheter and the predicate device.

Table 10.1. Subject and Predicate Devices Comparison Chart

Property	Subject Device Reflexion Spiral catheter (this 510(k))	Predicate Device Irvine Biomedical, Inc. Optima Catheter K042775
Indications for Use	(b)(4) Confidential and Proprietary Information	The Inquiry™ Optima™ Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiologic studies. The Optima™ catheters are to be used to map the atrial regions of the heart.

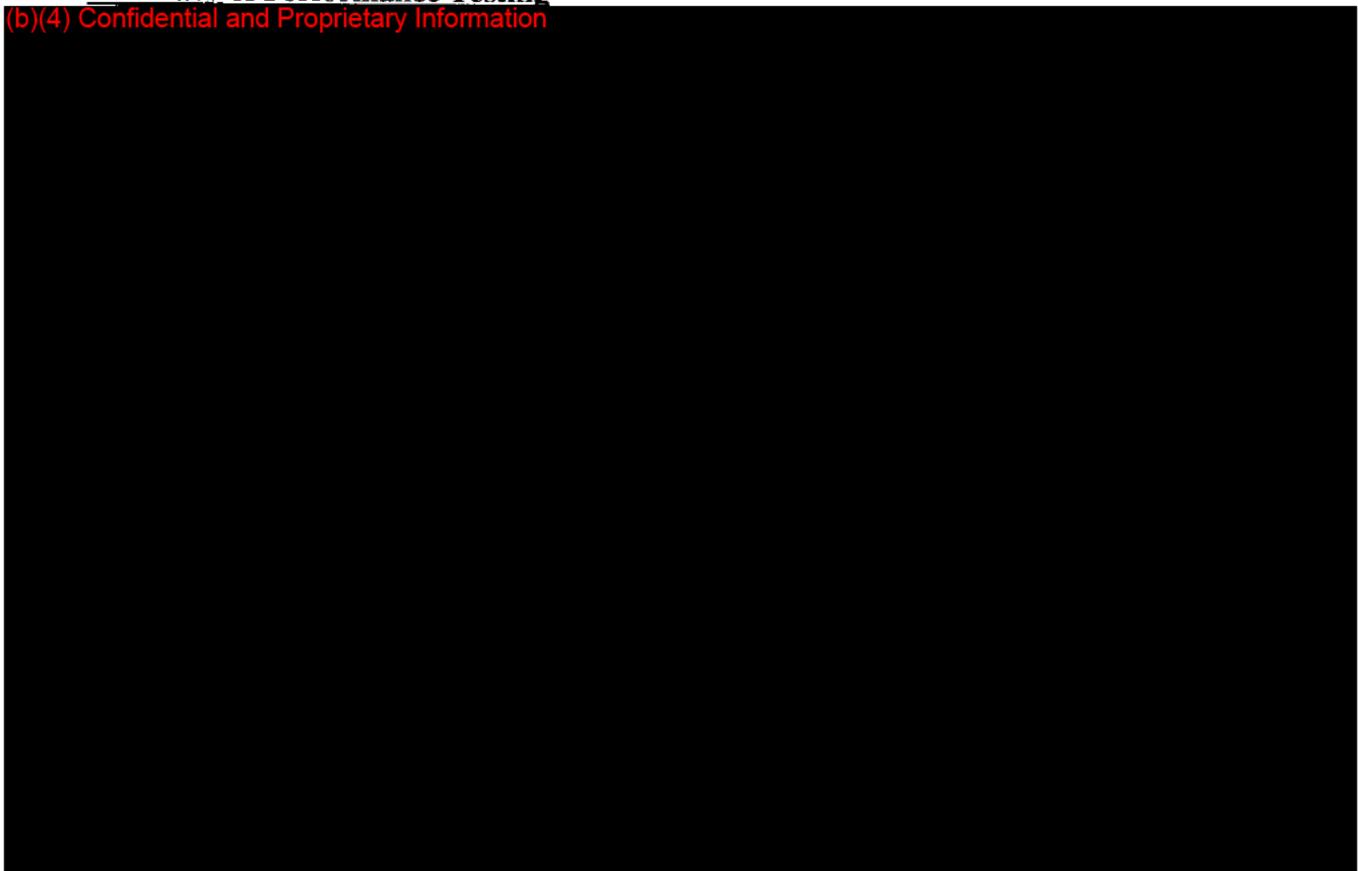
Section 10

Executive Summary

Property	Subject Device: Reflexion Spiral Catheter (this 510(k))	Predicate Device Optima Catheter K042775
Device Characteristics	(b)(4) Confidential and Proprietary Information	
Catheter design		Uni-directional, variable radius circular mapping catheter
Outer diameter		7F w/5F distal loop
Guiding introducer compatibility		7F or larger
Electrodes		20 electrodes in 10 bipolar pairs 1 mm intra-pair spacing
Radiopaque markings		Catheter shaft and electrodes are radiopaque
Steerable		Yes
Deflection direction		Unidirectional
Usable lengths		180° Deflection 110cm
Loop diameter		Variable 25mm to 15mm diameter
Packaging		Dual barrier

Summary of Performance Testing

(b)(4) Confidential and Proprietary Information



Conclusion

The Reflexion Spiral catheter uses similar technology and has similar intended use, materials and dimensional characteristics to the predicate device. Through the comparison data provided in **Table 10.1** above and supporting bench and animal data provided in **Sections 18** and **19**, St. Jude Medical considers the Reflexion Spiral Variable Radius Mapping Catheter to be substantially equivalent to the Inquiry Optima Electrophysiology Catheter marketed by Irvine Biomedical Inc, a St. Jude Medical company.

DEVICE DESCRIPTION**Device Description**

The Reflexion Spiral catheter is designed specifically for cardiac mapping or pacing procedures that use hemostasis introducers and a SJM Response™ extension cable that is connected to a compatible ECG recorder. The Reflexion Spiral catheter is a catheter with nineteen 1mm ring electrodes, and one 2mm tip electrode, a deflectable distal segment with bi-directional asymmetric curves, and a variable radius distal loop.

- The Reflexion Spiral catheter electrode configuration provides electrical mapping of the atrial regions of the heart. The electrode rings and polymer material are radiopaque to improve fluoroscopic visualization.
- The Reflexion Spiral catheter features a deflectable loop at the distal end of the catheter. The loop diameter can be varied between 25mm and 15mm to map the atria of the heart. The distal loop is designed with a soft polymer (atraumatic) to minimize vessel trauma. Refer to **Figure 11.1 and 11.2** for a comparison of the two devices loop deflections.

Figure 11.1: Reflexion Spiral and IBI Inquiry Optima loop (undeflected)

(b)(4) Confidential and Proprietary Information

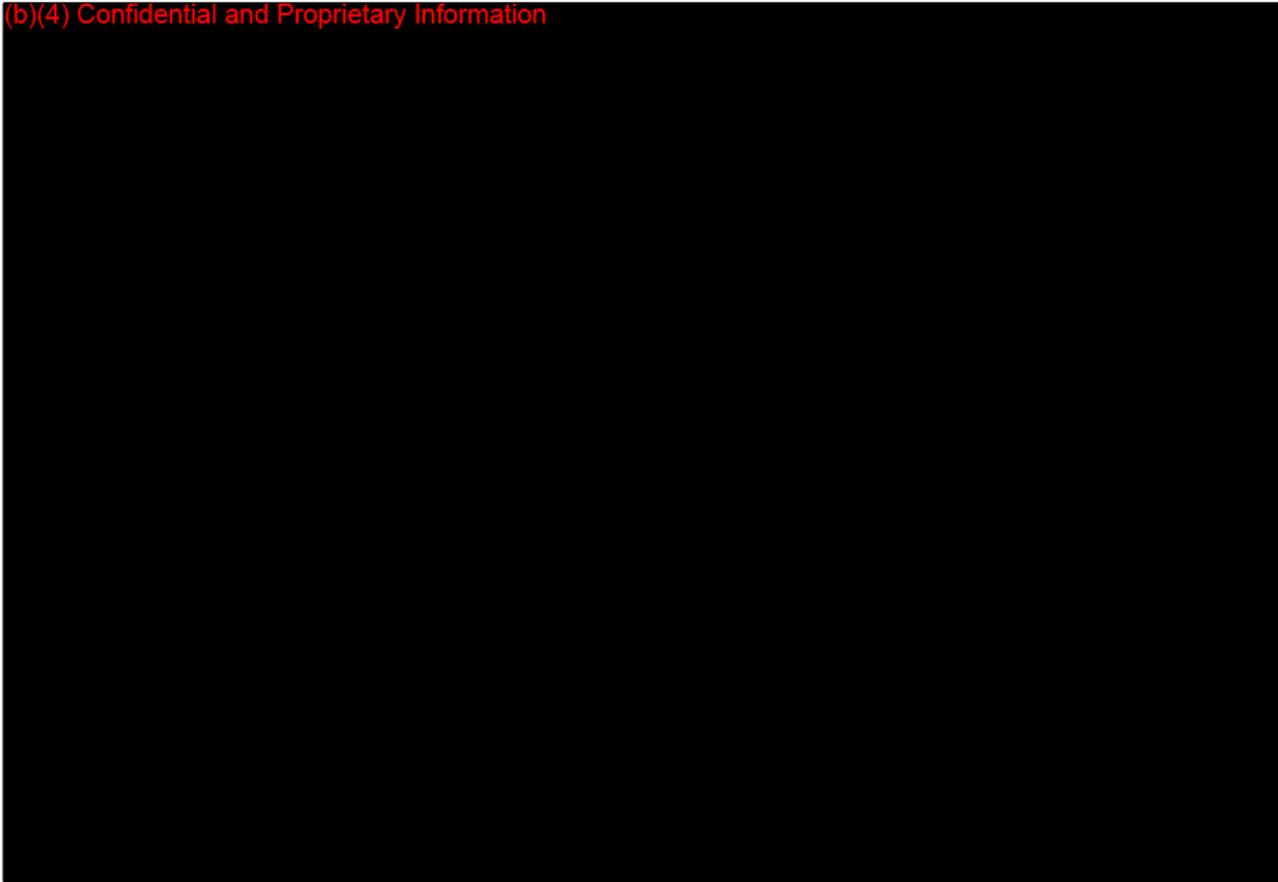
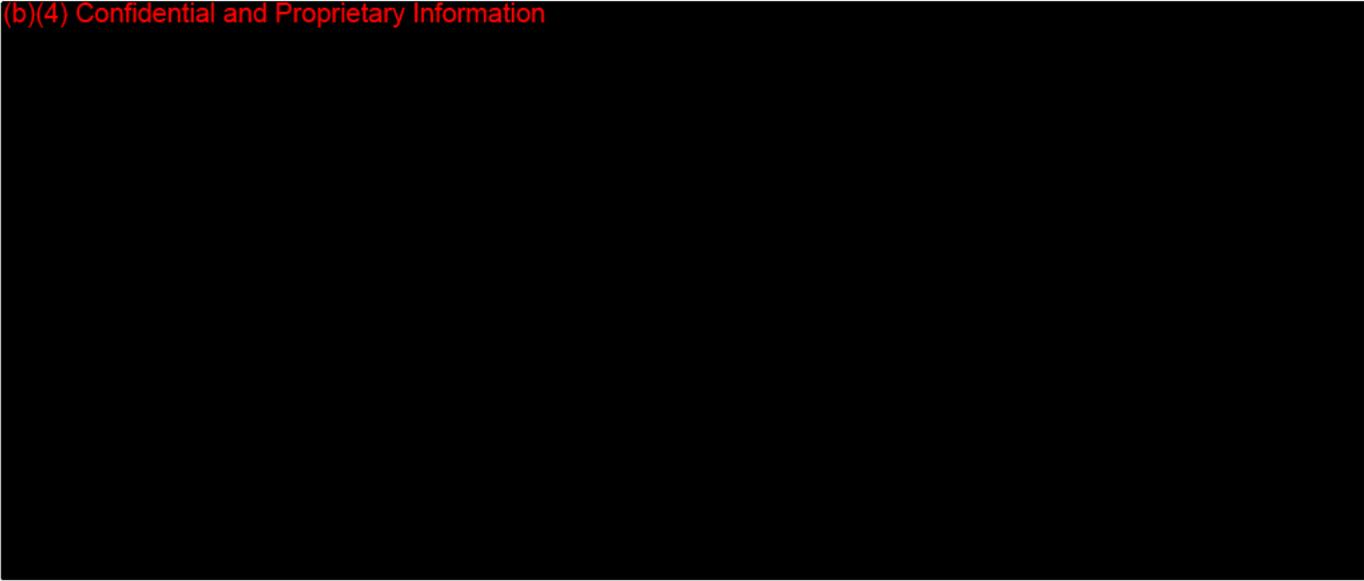


Figure 11.2: Reflexion Spiral and IBI Inquiry Optima Loop (deflected)

(b)(4) Confidential and Proprietary Information

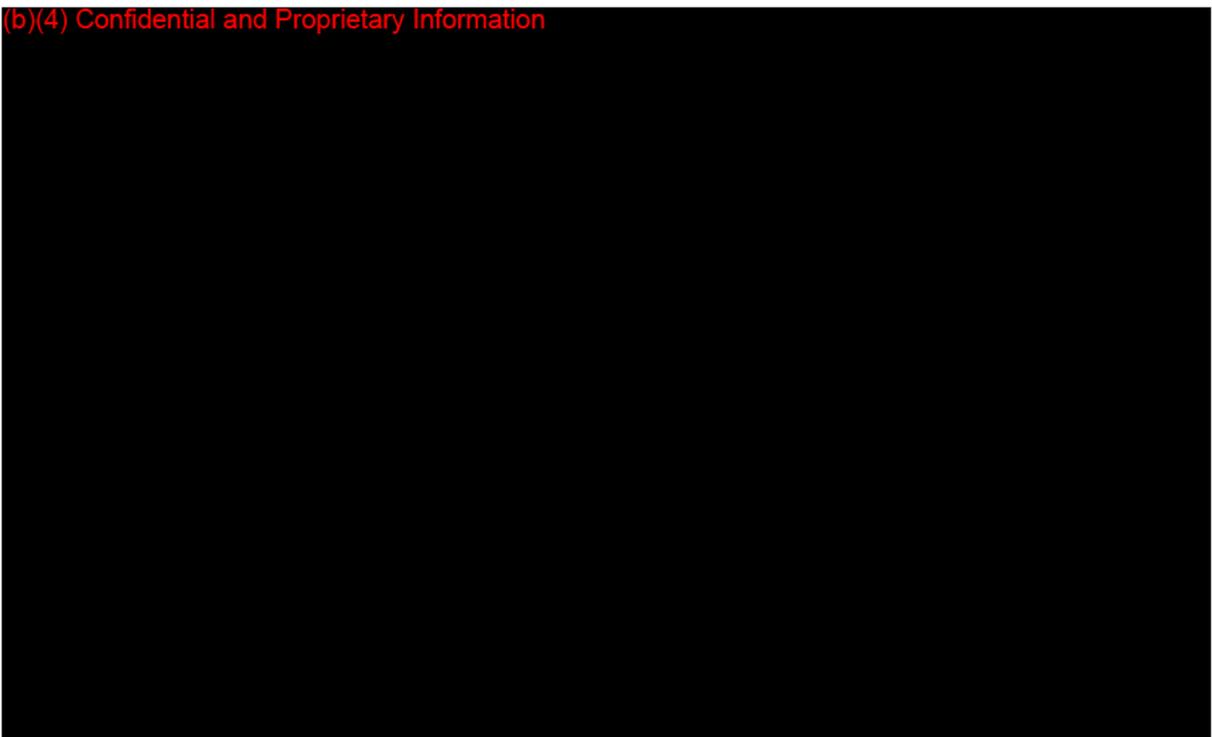


Predicate Comparison

The handle of the Reflexion Spiral is predicated from the SJM Safire™ Bidirectional Ablation catheter approved under P960016, Supplement 014 (included as a reference predicate).

Figure 11.3: SJM Reflexion Spiral and SJM Safire handle comparison

(b)(4) Confidential and Proprietary Information



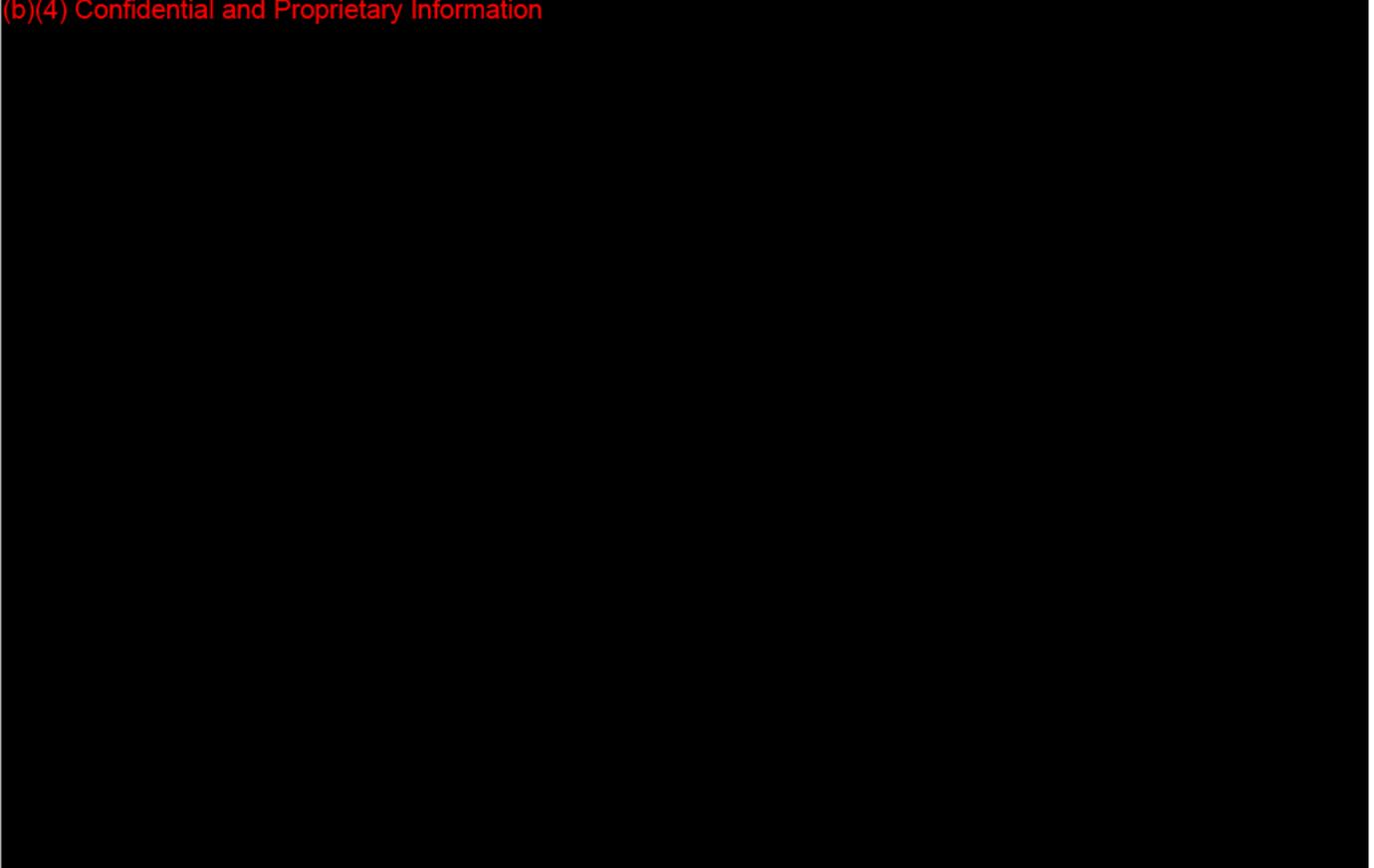
Predicate Comparison

The following is a description with pictures of the Reflexion Spiral catheter and the predicate IBI Inquiry Optima proximal handle designs and the method of shaft/loop deflection of each.

- **Proximal Handle**

Refer to **Figures 11.4 and 11.5** for a comparison of the Reflexion Spiral and the Inquiry Optima catheter handle views.

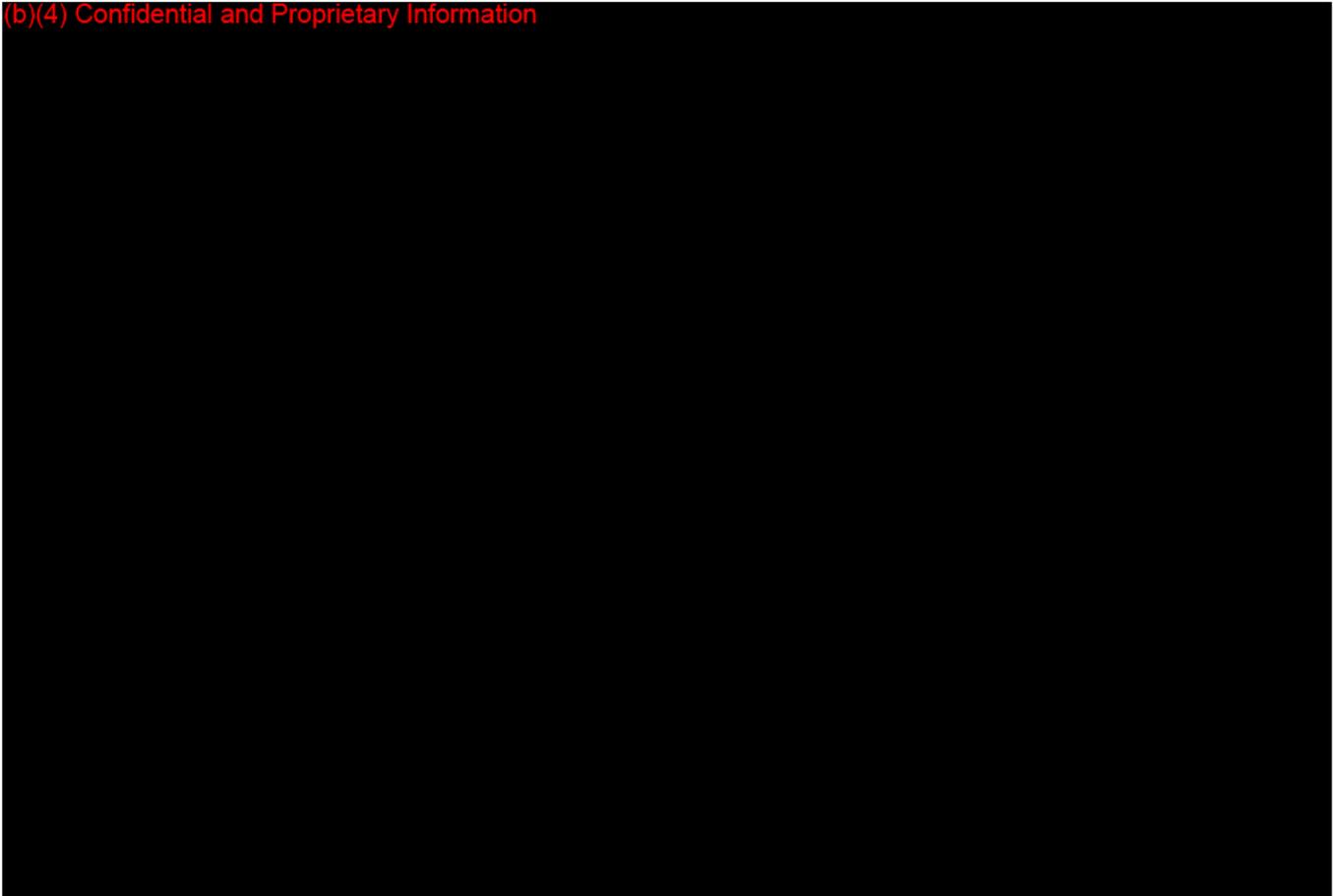
(b)(4) Confidential and Proprietary Information



By referring to the pre-printed diagrams on the Reflexion Spiral handle, the end user can deflect the shaft using the shaft actuator by depressing with the thumb or forefinger. The shaft will deflect bidirectionally to a 90° sweep or 180° small curl configuration.

The loop radius is enlarged or reduced by pushing/pulling the loop actuator forward or backward.

(b)(4) Confidential and Proprietary Information



The Shaft Actuator for the Inquiry Optima device deflects the shaft by pushing/pulling with the thumb and forefinger. The shaft will deflect unidirectionally to a 180° Sweep.

The loop radius is enlarged or reduced by rotating the Loop Actuator of the Inquiry Optima device in a clockwise or counterclockwise direction.

Although the method by which the two devices achieve loop radius and loop positioning vary, they have equivalent abilities to provide the range of control that is needed for diagnostic mapping or pacing functions. The Reflexion Spiral catheter handle was designed similar to the SJM Safire Ablation catheter handle, with the addition of the second actuator for loop deflection. The effectiveness of the Reflexion Spiral catheter handle design was verified in an animal study. Refer to **Section 19 and Appendix H**.

Section 11**Device Description****Product Specifications**

Refer to **Table 11.1** for the Reflexion Spiral catheter product specifications.

Table 11.1: Reflexion Spiral Catheter Product Specifications

Property	Reflexion Spiral Catheter
Catheter design	(b)(4) Confidential and Proprietary Information
Outer diameter	
Guiding introducer compatibility	
Electrodes	
Radiopaque markings	
Steerable	
Deflection direction	
Usable length	
Loop diameter	
Packaging	

The Reflexion Spiral Catheter is provided sterile and is intended for single use only.

Device engineering drawings are provided in **Appendix A**.

Principles of Operation

The Reflexion Spiral catheter is used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies.

The catheter is inserted into the femoral artery through an appropriately sized hemostasis introducer. The catheter is guided through the sheath into the left or right atrium using fluoroscopic imaging to measure the electrical potentials which are then displayed on an ECG monitor. The resulting signals are analyzed to determine whether there are abnormalities in the signals. The Reflexion Spiral catheter can be used for mapping or pacing of the heart.

Features of the Reflexion Spiral catheter that makes it particularly useful for this indication for use is the ability to move bi-directionally and the ability to change the radius of the loop with a single device. The bi-directionality permits greater dexterity in positioning the loop into areas of the atrial anatomy. The shaft deflection (90° Sweep or 180° Small Curl) and the variable radius loop (25mm to 15mm diameter) permits adjusting a single catheter into the heart with a wide range of geometries.

Human factors principles have been used in the design of the Reflexion Spiral catheter handle. The handle permits the cardiologist to manipulate, with one hand, the shaft for bi-directional deflection and variable loop radius.

SUBSTANTIAL EQUIVALANCE DISCUSSION

The predicate device referenced in this submission is the Inquiry Optima catheter cleared by Irvine Biomedical Inc, a St Jude company, as K042775.

Predicate Device Description:

Device: Irvine Biomedical Inc. Inquiry™ Optima™ Steerable Electrophysiology Catheter
510(k) Number: K042775

Brief Description:

The Inquiry™ Optima™ Steerable Electrophysiology Catheter is a flexible, radiopaque catheter with a variable number of electrodes with the first electrode located at the distal tip and the other band electrodes following at predetermined distances. A connecting cable is used to connect the catheter to electrogram devices. The catheter has a distal loop in a plane perpendicular to the catheter body. The circumferential shape or loop allows the electrophysiologist to record the potentials of cardiac structures without changing the position of the catheter. The catheter shaft and/or loop is steerable by manipulating the handle. The placement of the electrodes around the entire circumference of the distal loop also assists the electrophysiologist during fluoroscopy with visualization. The distal loop shape is easily straightened with the thumb and forefinger to facilitate insertion into sheaths and introducers. Once the catheter is extended beyond the sheath, the catheter resumes its pre-formed shape. The device is supplied sterile and is intended for single use only.

Table 12.1 provides a comparison of device characteristics, materials, sterilization and packaging between the proposed Reflexion Spiral catheter and the predicate device.

Table 12.1 Comparison Chart

Property	Subject Device: Reflexion Spiral Catheter (this 510(k))	Predicate Device Inquiry Optima Catheter K042775
Indications for Use	(b)(4) Confidential and Proprietary Information	The Inquiry™ Optima™ Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiologic studies. The Optima™ catheters are to be used to map the atrial regions of the heart.
Device Characteristics		
Catheter design		Uni-directional, variable radius circular mapping catheter
Outer diameter		7F w/5F distal loop
Guiding introducer compatibility		7F or larger
Electrodes		20 electrodes in 10 bipolar pairs 1 mm intra-pair spacing

Reflexion Spiral™ Variable Radius Catheter
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Section 12

Substantial Equivalence Discussion

Property	Subject Device: Reflexion Spiral Catheter (b)(4) Confidential and Proprietary Information	Predicate Device: Inquiry Optima Catheter K042775
Radiopaque markings	(b)(4) Confidential and Proprietary Information	Catheter and electrodes are radiopaque
Steerable	(b)(4) Confidential and Proprietary Information	Yes
Deflection direction	(b)(4) Confidential and Proprietary Information	Unidirectional
Usable lengths	(b)(4) Confidential and Proprietary Information	180° Deflection
Loop diameter	(b)(4) Confidential and Proprietary Information	110cm
Packaging	(b)(4) Confidential and Proprietary Information	Variable 25-15mm diameter
		Dual barrier

A copy of the predicate device labeling is contained in **Appendix B**.

FDA SUBSTANTIAL EQUIVALENCE FLOWCHART EVALUATION

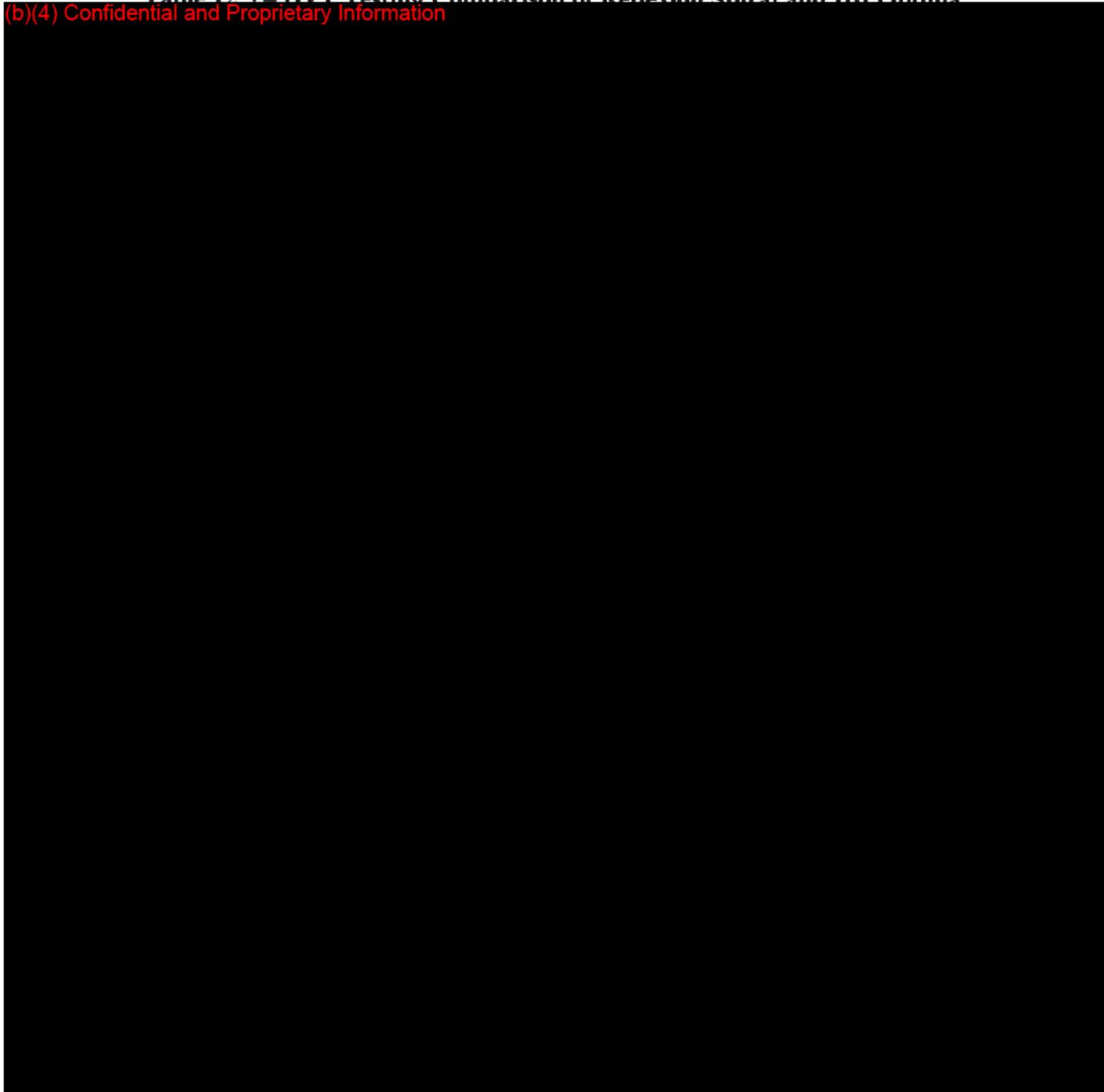
The Reflexion Spiral catheter was compared to the IBI Optima catheter by using the 510(k) "Substantial Equivalence" Decision-Making Process (Detailed) Flowchart. **Table 12.2** summarizes the applicable questions from this flowchart.

Table 12.2 – Equivalence Flowchart Evaluation

#	Question	Answer/Justification	Action
3.	Does the device have the same indication statements?	Yes. The Reflexion Spiral catheter has an indication statement for Use statement equivalent to the Irvine Biomedical, Inc. Inquiry Optima catheter.	Go to question 5
5.	Does new device have same technological characteristics, e.g., design, materials, etc.?	No. The Reflexion Spiral catheter utilizes many of the same materials and design principles, but incorporates a unique handle design, modified shaft/loop deflection method, a softer durometer loop, and a different packaging design.	Go to question 6
6.	Could the new characteristics affect safety or effectiveness?	Yes. The new characteristics of the Reflexion Spiral catheter could affect safety or effectiveness.	Go to question 8
8.	Do the new characteristics raise new types of safety or effectiveness questions?	No. The new characteristics of the Reflexion Spiral catheter were evaluated through a Risk and Hazard Analysis Report and do not raise new types of safety or effectiveness questions when compared to the predicate device. Refer to Appendix D .	Go to question 9
9.	Do accepted scientific methods exist for assessing effects of the new characteristics?	Yes. The new characteristics have been evaluated using established scientific methods such as electrical continuity and isolation; catheter leakage current; catheter deflection durability; distal tip shaft buckle force; pressurized fluid ingress; biocompatibility testing, etc.	Go to question 10
10.	Are performance data available to assess effects of new characteristics?	Yes. Performance data for the Reflexion Spiral catheter have been evaluated, and are provided in Sections 18 and 19.	Go to question 11
11.	Performance data demonstrate equivalence?	Yes. The performance data provided in Sections 18 and 19 demonstrate that the Reflexion Spiral catheter is equivalent to the predicate device.	Substantially equivalent

Table 12.3 – DVT Testing Comparison of Reflexion Spiral and IRI Optima

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CONCLUSION

Through the comparison chart provided in **Table 12.1**, the equivalence flowchart evaluation in **Table 12.2**, DVT testing comparison chart in **Table 12.3**, and supporting bench and animal data provided in **Sections 18 and 19**, SJM considers the Reflexion Spiral™ Variable Radius Catheter to be substantially equivalent to the Irvine Biomedical, Inc. Inquiry™ Optima™ Steerable Electrophysiology Catheter. The Reflexion Spiral catheter uses similar technology and has similar intended use, materials and dimensional characteristics as the predicate devices.

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PROPOSED LABELING

A copy of the user manual that includes the Instructions for Use (IFU), along with the pouch and box label for the Reflexion Spiral catheter are provided in **Appendix C**.

Section 14

Sterilization, Packaging and Shelf Life

STERILIZATION, PACKAGING AND SHELF LIFE

A. Sterilization

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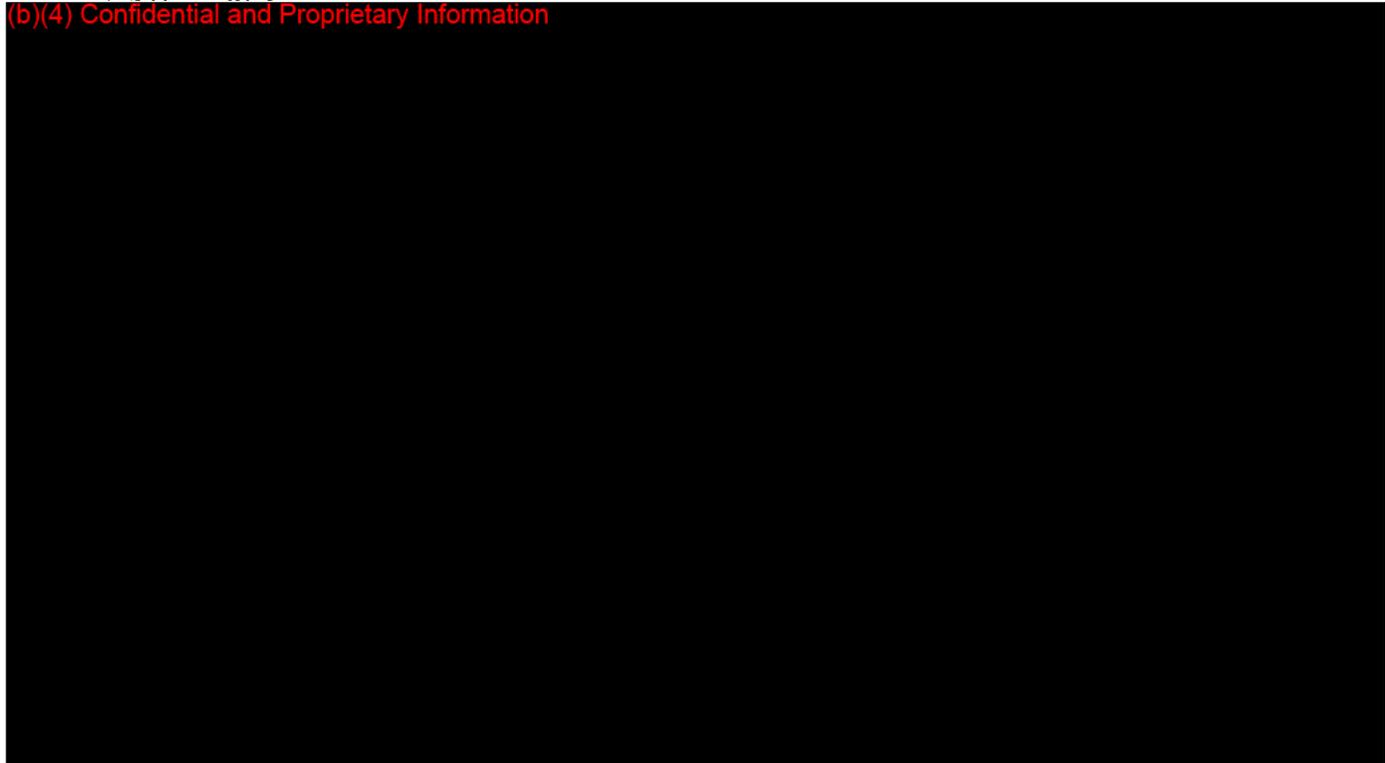


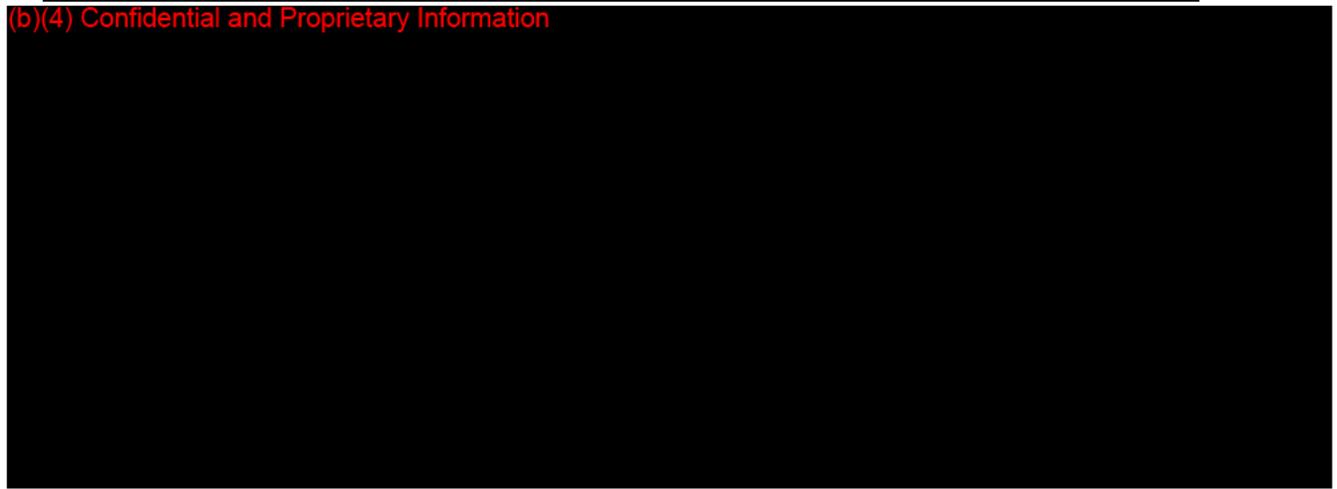
Table 14.1: Results of LAL Bacterial Endotoxin

Lot Number	Acceptance Criteria Endotoxin Limit	Endotoxin Test Result	Conclusion
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(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



Section 14

Sterilization, Packaging and Shelf Life

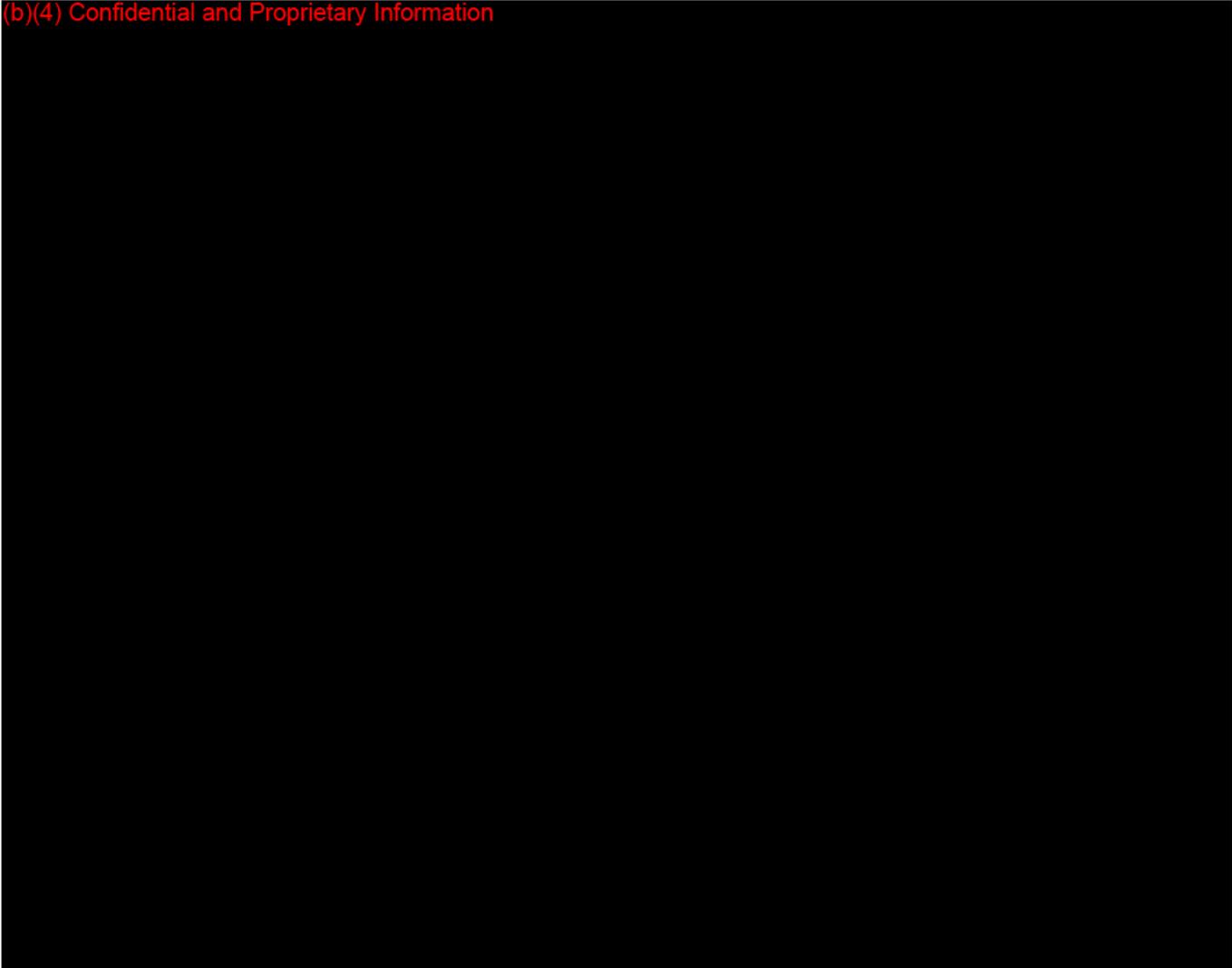
Bioburden levels will be monitored quarterly as specified in SJM General Procedure (GP) 1731 using a test method developed and validated according to ANSI/AAMI/ISO 11737-1, *Sterilization of medical devices – Microbiology methods, Part 1: Estimation of the population of microorganisms on products*.

The device is not intended for sterilization by the user

Note: The Reflexion Spiral catheter is marketed for Single Use Only.

B. Packaging Validation

(b)(4) Confidential and Proprietary Information



Summary of Test Results: Refer to **Tables 14.3**.

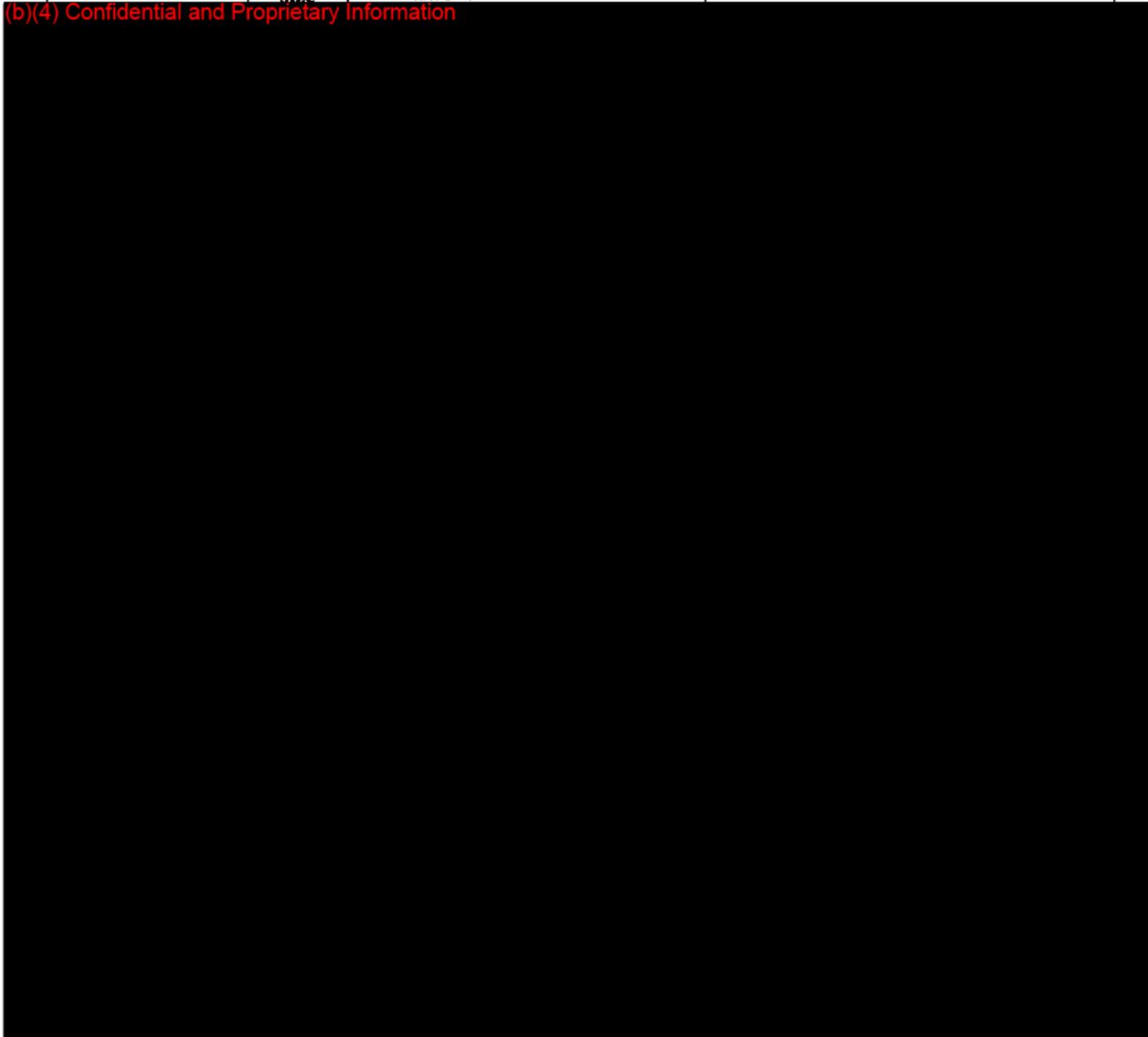
Section 14

Sterilization, Packaging and Shelf Life

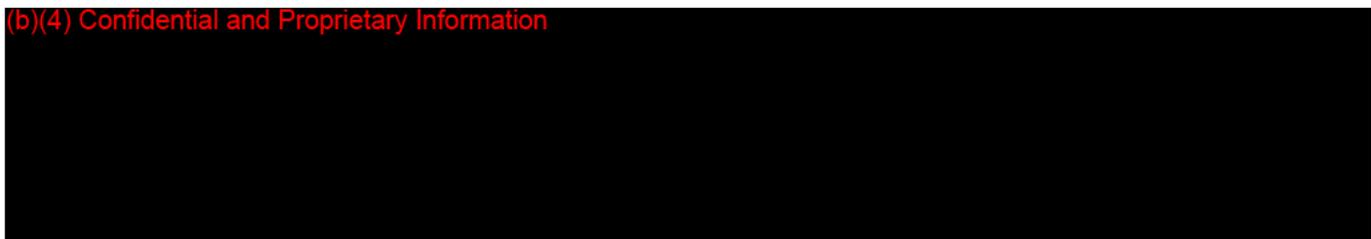
Table 14.3: Summary of Safire Shipping (b)(4) Accelerated Aging Test Results Report (b)(4)

Test	Sample size	Acceptance Criteria	Results/Deviations
------	-------------	---------------------	--------------------

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



Section 14

Sterilization, Packaging and Shelf Life

C. Shelf Life

(b)(4) Confidential and Proprietary Information

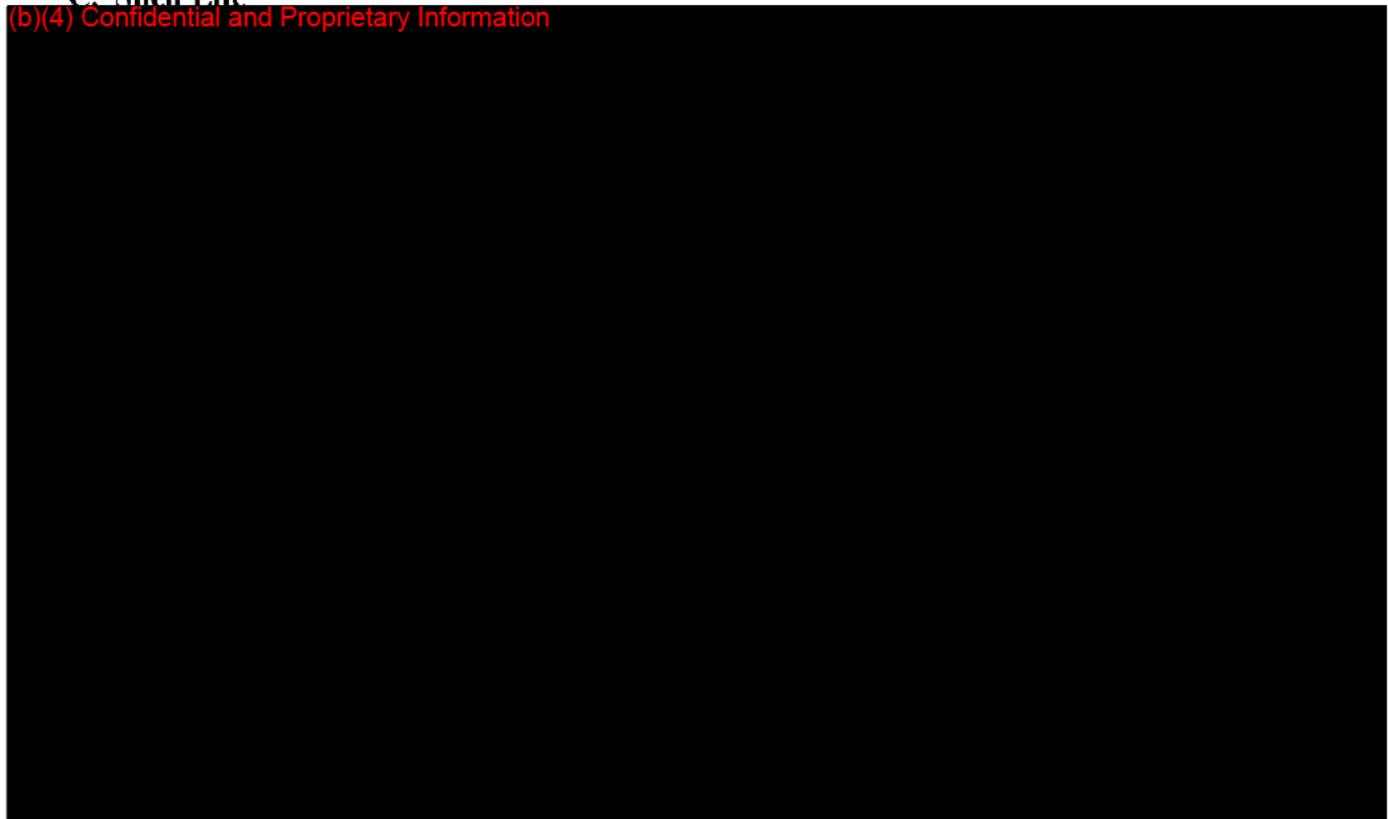


Table 14.4: Summary of Shelf Life Verification Testing

Test Type	Test Status	Test Result
(b)(4) Confidential and Proprietary Information		



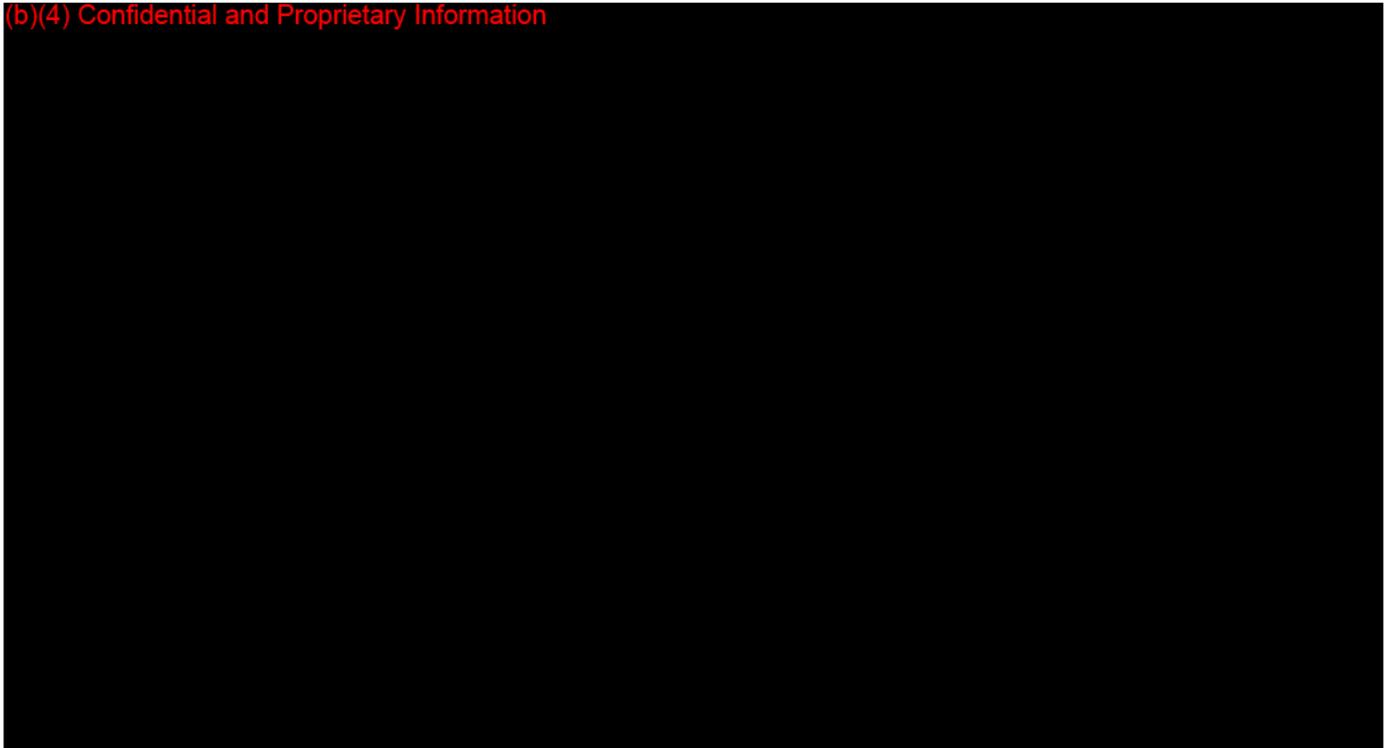
(b)(4) Confidential and Proprietary Information



Section 14

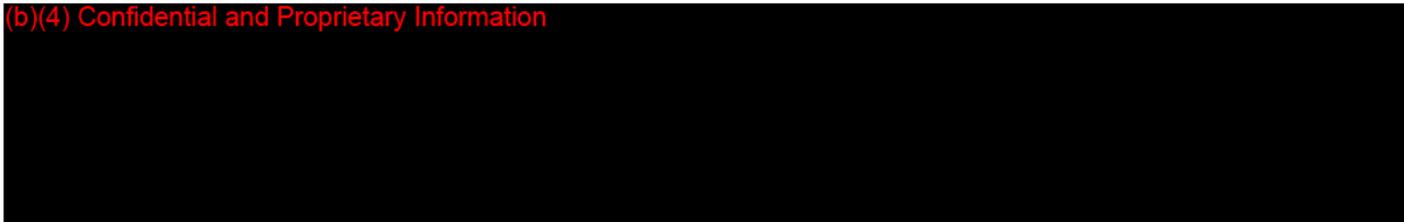
Sterilization, Packaging and Shelf Life

(b)(4) Confidential and Proprietary Information



CONCLUSION

(b)(4) Confidential and Proprietary Information



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BIOCOMPATIBILITY

According to ISO 10993-1, "Biological Evaluation of Medical Devices" fluid path contact components of the Reflexion Spiral catheter are classified as Externally Communicating Devices, Circulating Blood, with Limited Contact Duration (≤ 24 hours).

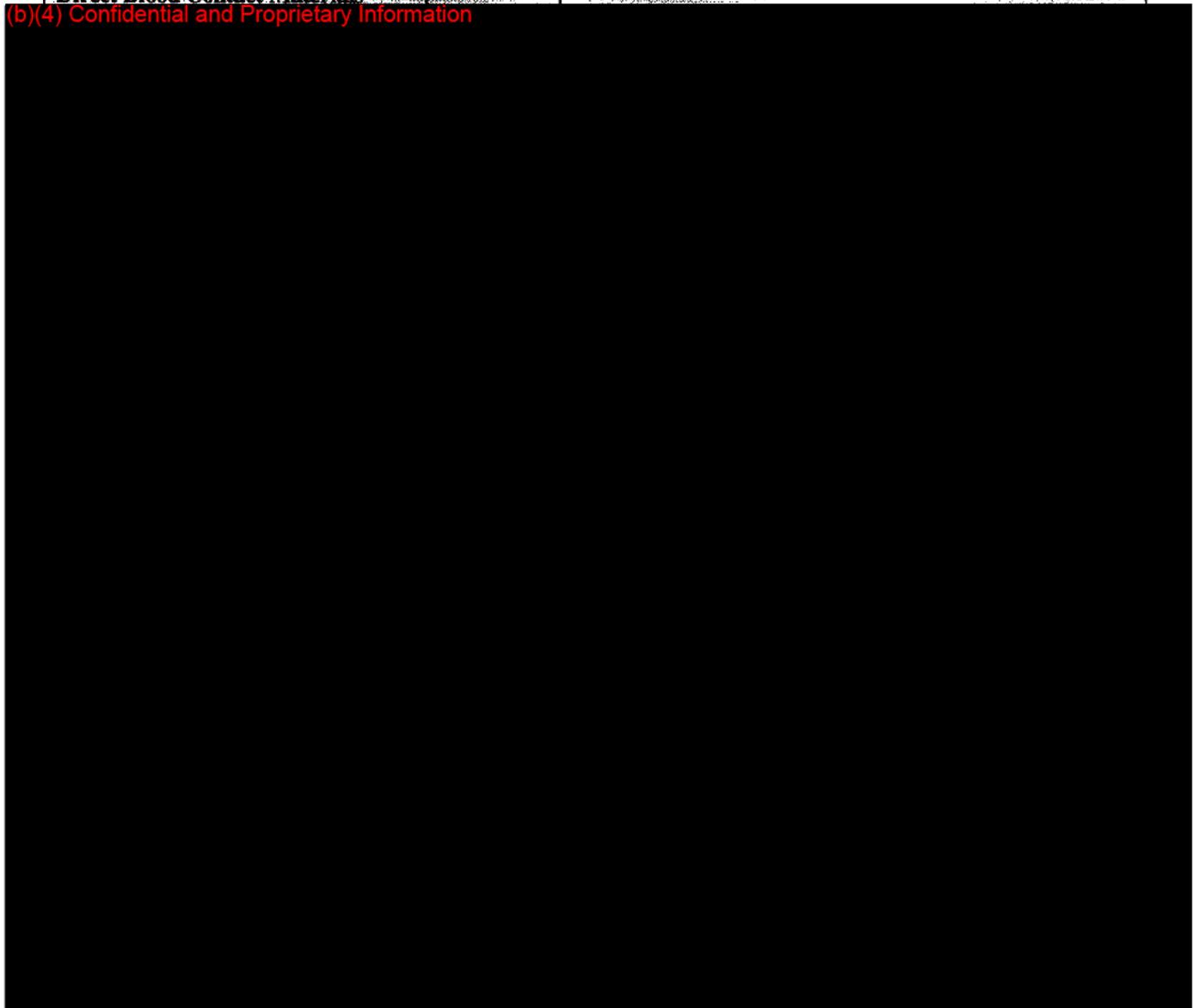
ISO 10993-1 requires consideration of direct and indirect blood contact materials. Indirect blood contact materials are defined as materials adjacent to or protected by a blood contact material which have a small potential of contacting blood, but are not in the circulating blood path.

Refer to **Table 15.1** for direct and indirect blood contact components of the Reflexion Spiral catheter.

Table 15.1: Reflexion Spiral Catheter Biocompatibility Testing

Component/Feature	Part #	Material
Direct Blood Contact Materials		

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Section 15

Biocompatibility

Biocompatibility Testing

Per ISO 10993-1 the tests below “shall be considered” for an external communicating medical device that has contact with tissue for limited duration (< 24 hours). Section 6 of ISO 10993-1 states:

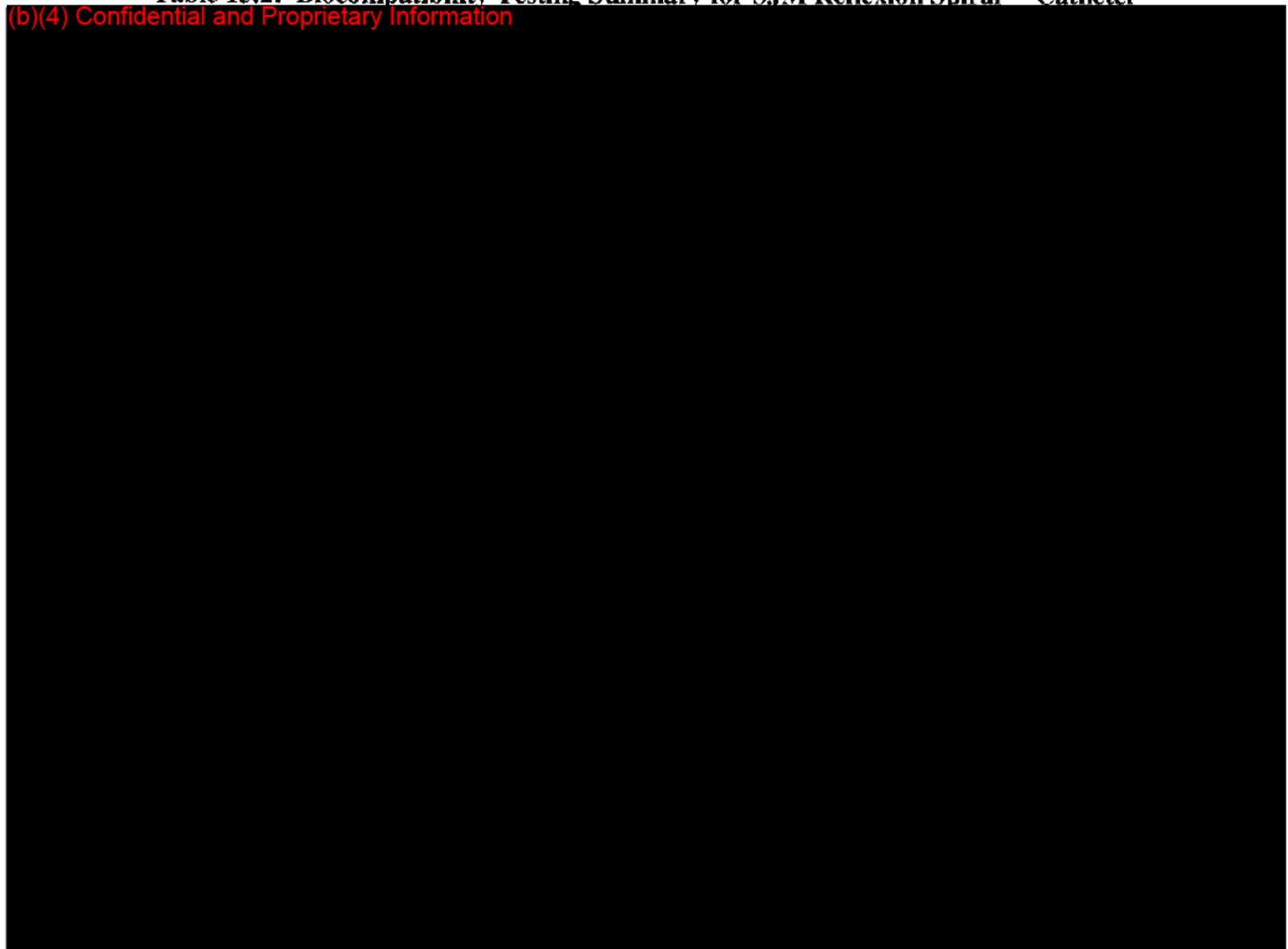
“...the evaluation may include both a study of the relevant experience and actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design.”

The Reflexion Spiral catheter uses a large number of components or materials that are substantially equivalent to the SJM Safire Ablation Catheter (P960016, S014). The table below summarizes the tests recommended for external communicating devices that have contact with tissue for limited duration and test reports from the Reflexion Spiral, or where appropriate the Safire Ablation Catheter, that show conformity with the ISO 10993 standards.

Refer to **Table 15.2**. Refer to **Attachment G**.

Table 15.2: Biocompatibility Testing Summary for SJM Reflexion Spiral™ Catheter

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(b)(4) Confidential and Proprietary Information



CONCLUSION

The above analysis of exposures, materials, and test results demonstrate that the Reflexion Spiral catheter meets biocompatibility standards.

Section 16

Software

SOFTWARE

This section is not applicable.

The Reflexion Spiral catheter does not contain software.

Section 17

Electromagnetic Compatibility and Electrical Safety

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

(b)(4) Confidential and Proprietary Information

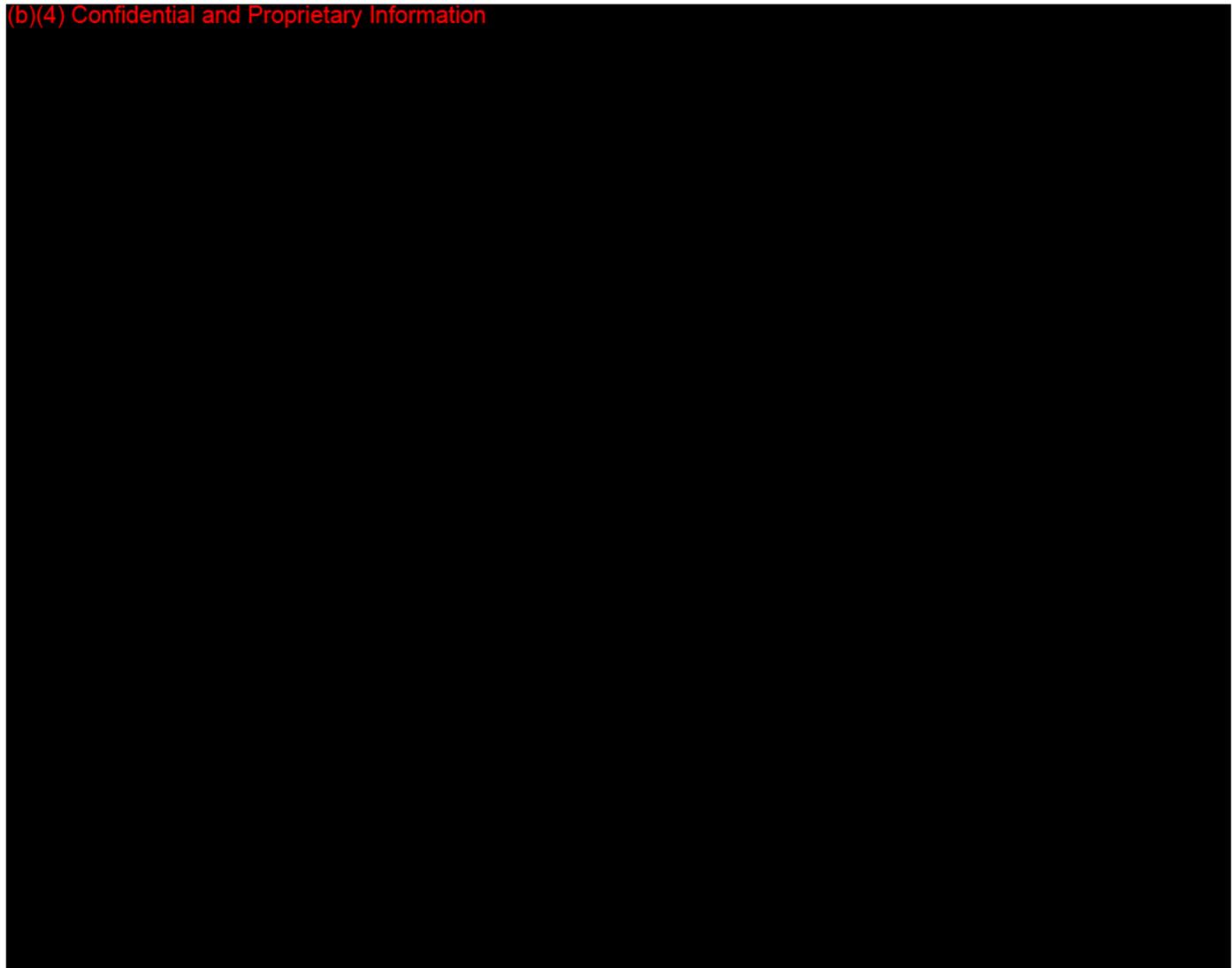


CONCLUSION

The results of the above tests successfully demonstrate that the Reflexion Spiral catheter meets electrical standards. For details and results of testing, refer to **Section 18**.

PERFORMANCE TESTING – BENCH

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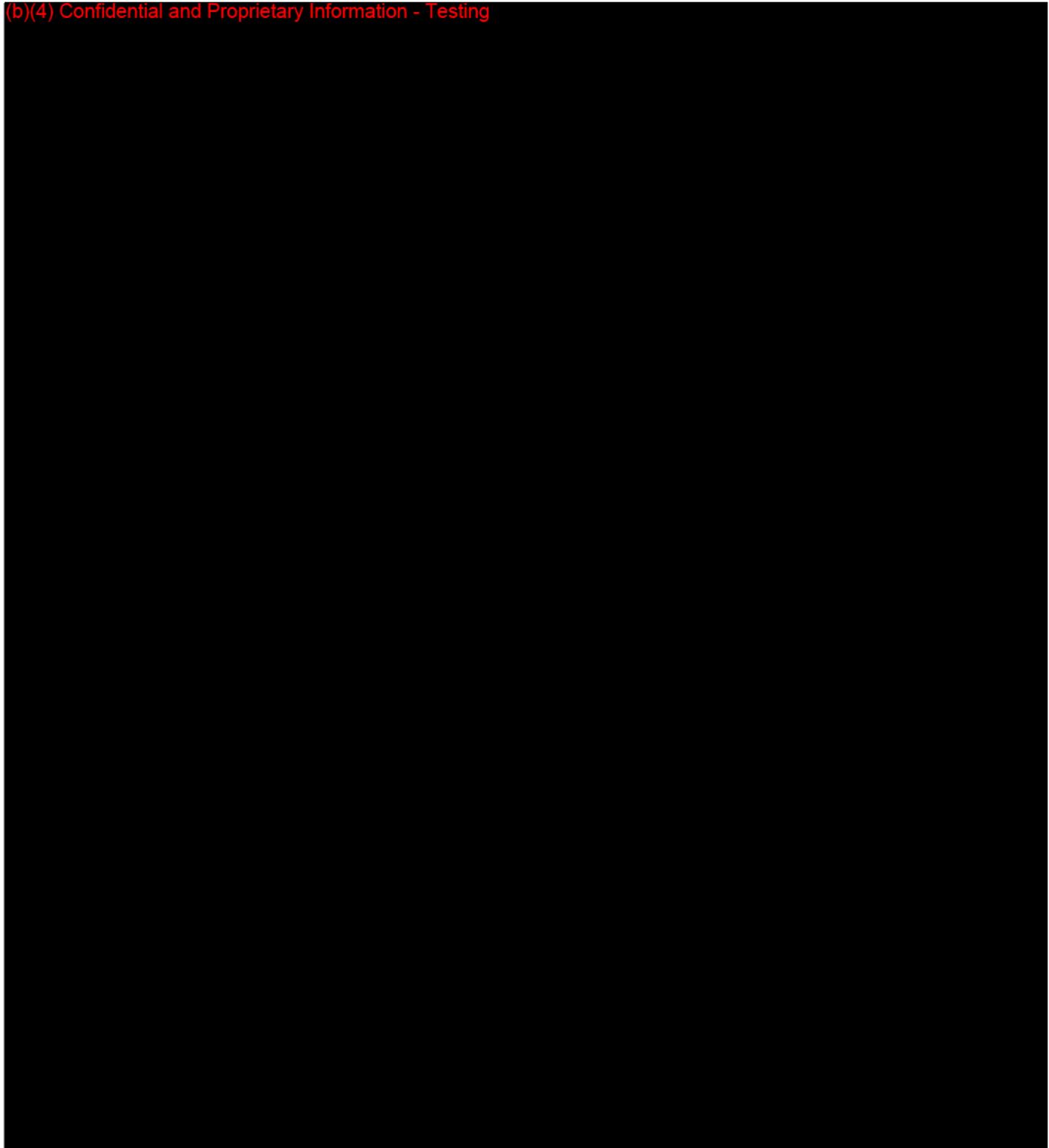
Section 18

Performance Testing - Bench

Design Verification testing was completed in the following sequence. Refer to **Table 18.1**.

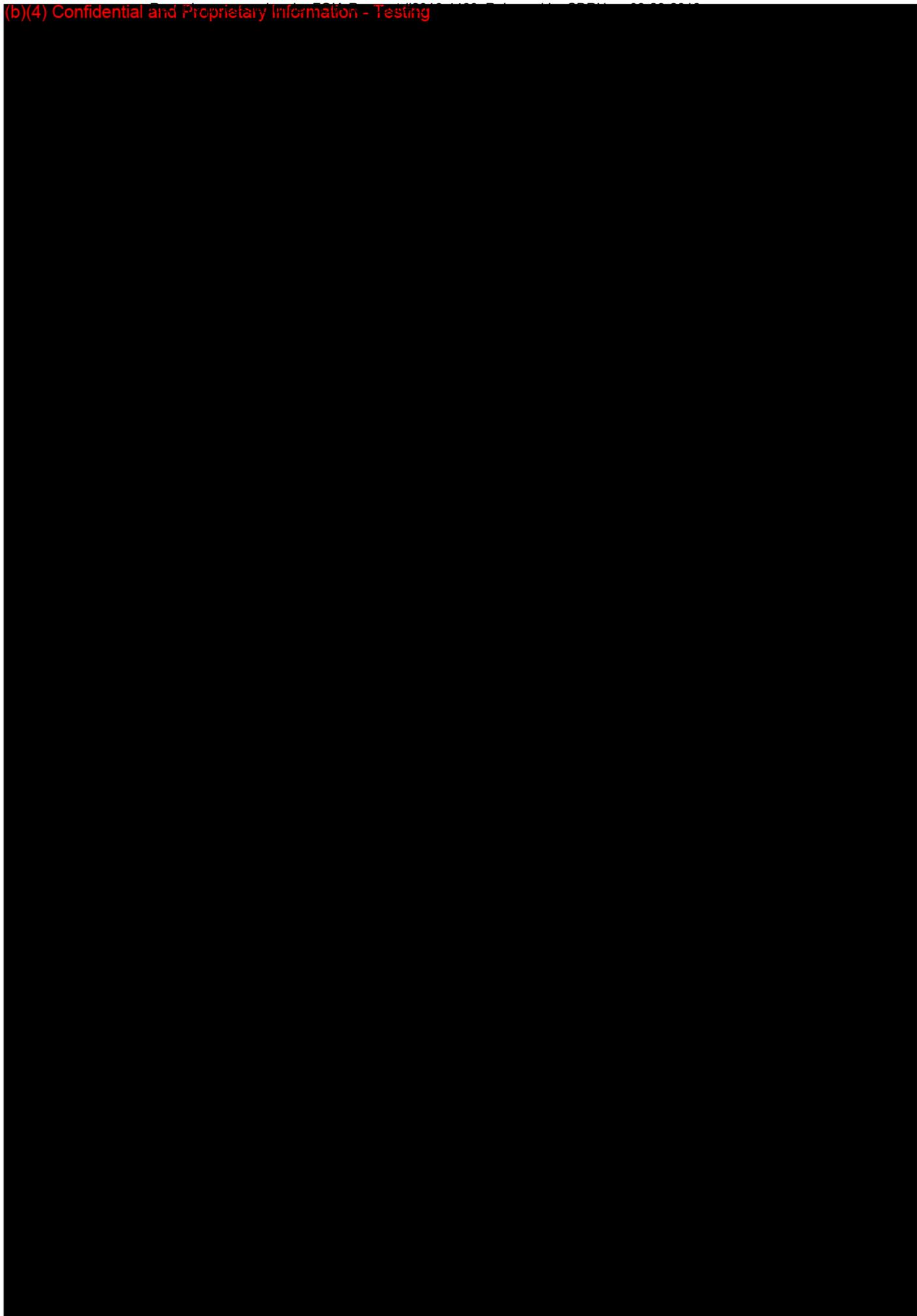
Table 18.1: Testing Sequence

(b)(4) Confidential and Proprietary Information - Testing

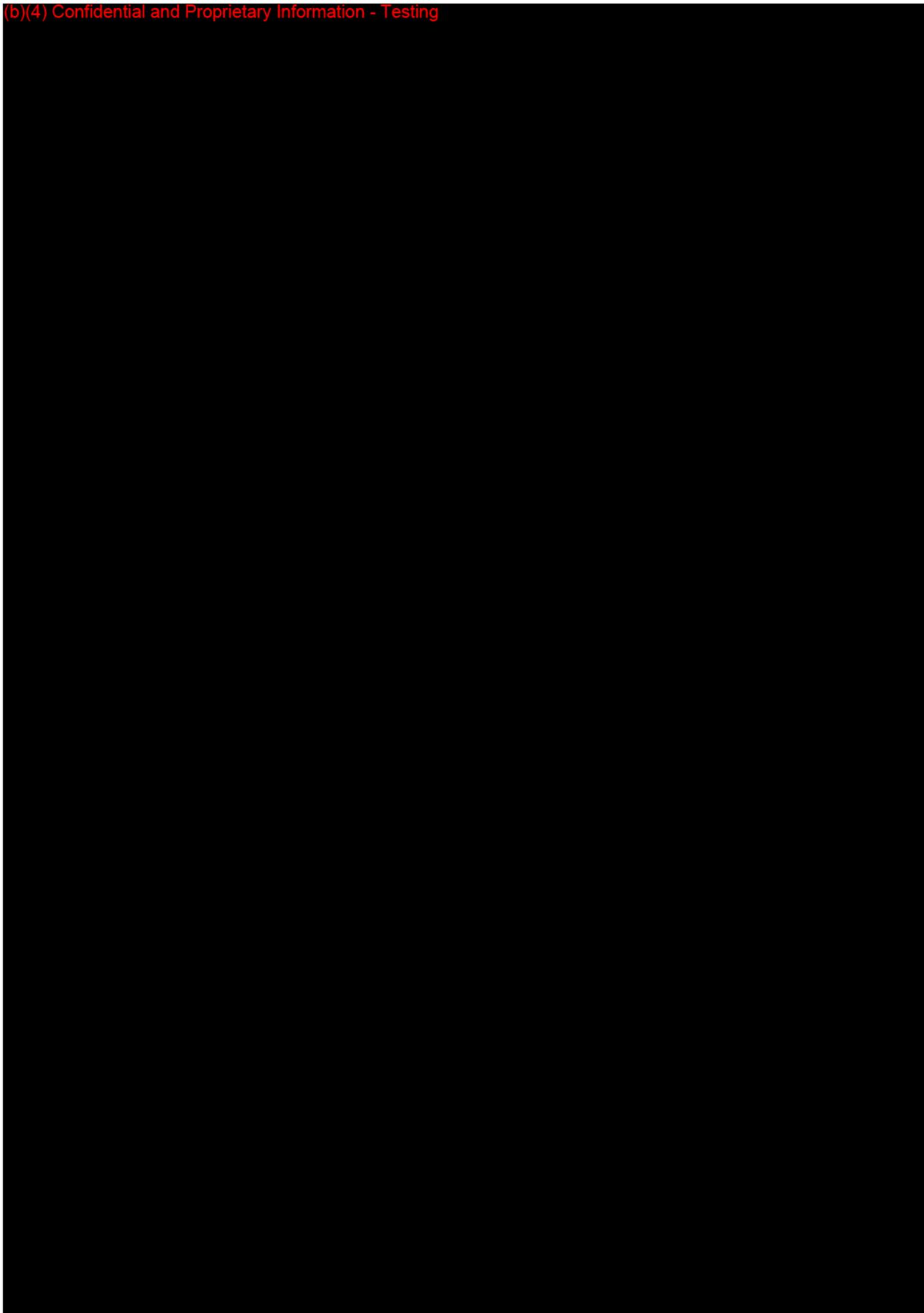


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Section 18 **Performance Testing - Bench**



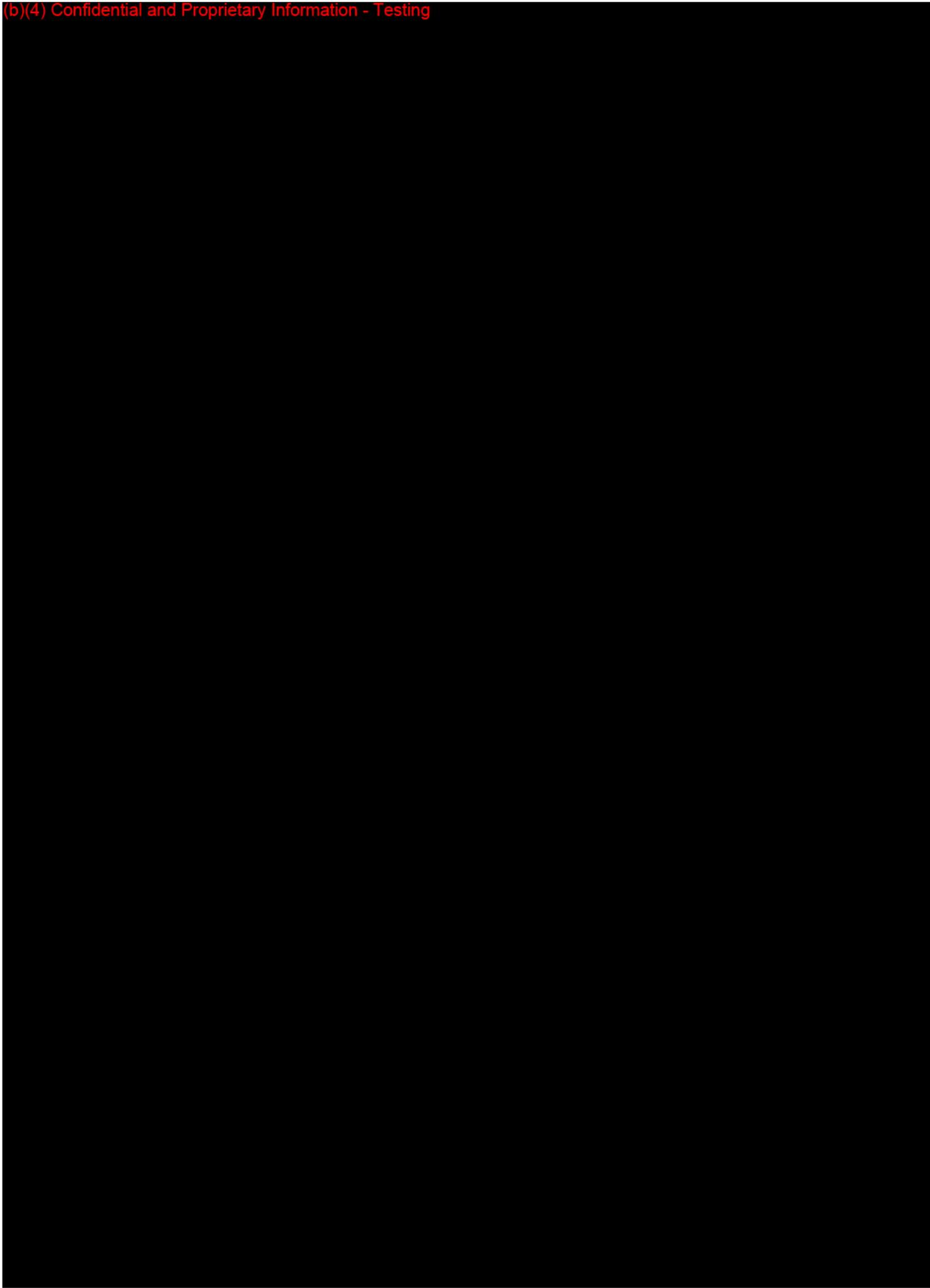
(b)(4) Confidential and Proprietary Information - Testing



Section 18 Performance Testing - Bench

Section 18

(b)(4) Confidential and Proprietary Information - Testing



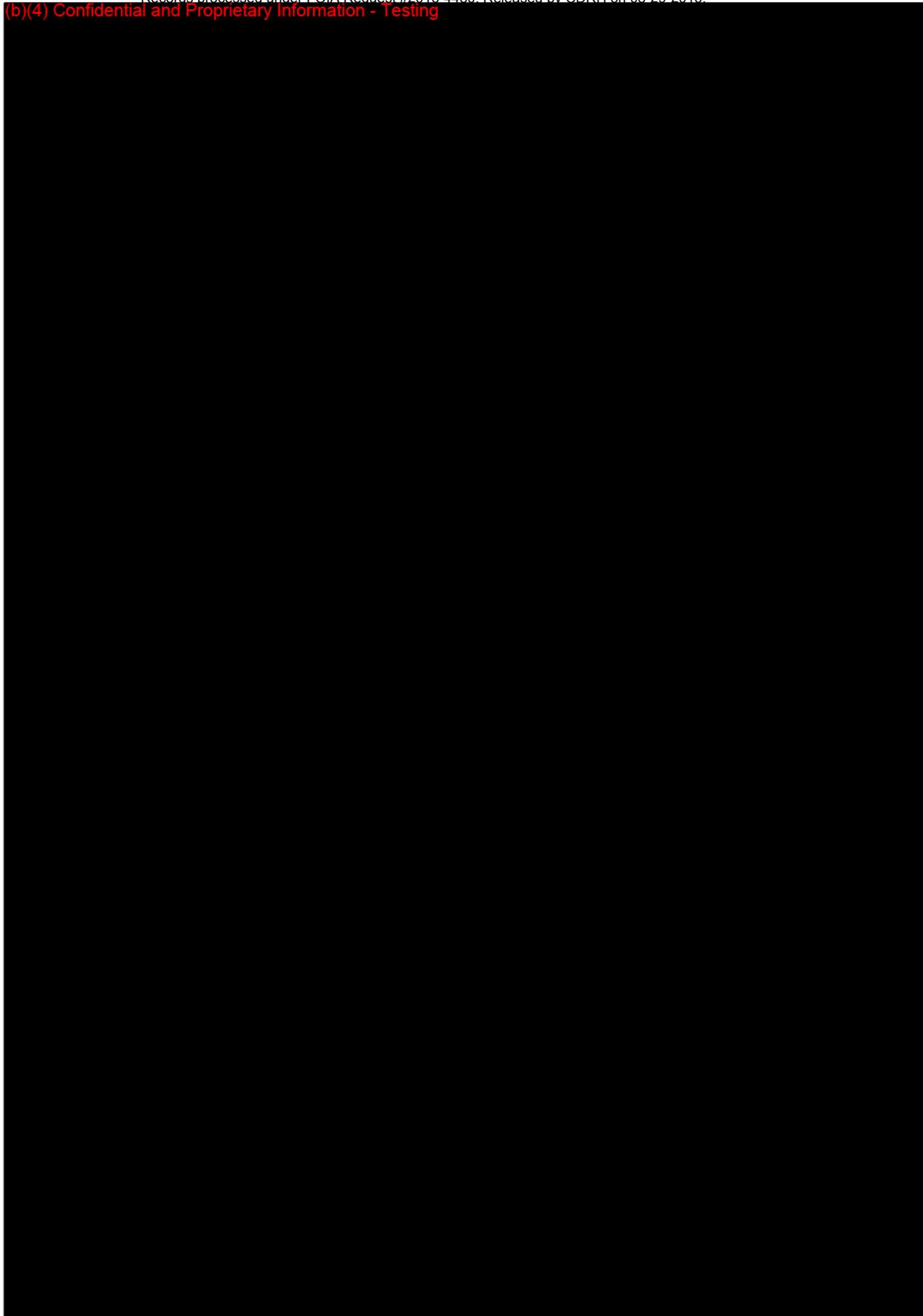
Performance Testing - Bench

Section 18

(b)(4) Confidential and Proprietary Information - Testing

Performance Testing - Bench

Section 18



Section 18

Performance Testing - Bench

CONCLUSION

The above test results demonstrate that the Reflexion Spiral catheter meets the device specifications, including simulated use. Refer to **Appendix E** for a copy of the complete Design Verification Test Report.

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PERFORMANCE TESTING – ANIMAL

(b)(4) Confidential and Proprietary Information - Testing



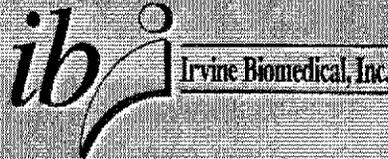
Section 20

Performance Testing - Clinical

PERFORMANCE TESTING - CLINICAL

This section is not applicable.

The St Jude Medical Reflexion Spiral catheter has the equivalent clinical performance to the Irvine Biomedical Inquiry™ Optima™ Steerable Electrophysiology Catheter (K042775)



IBI INQUIRY™ OPTIMA™ STEERABLE DIAGNOSTIC CATHETER

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 **Manufacturer:**
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2375 Morse Avenue
Irvine, California 92614 USA
Tel: (949) 851-3053
Fax: (949) 851-3062

 **European Authorized Representative:**
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The Corporate Village
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Avenue De Vincilaan, 11, Box F1
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US Customer Service:
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USA: (800) 253-9073
In MN Tel: (952) 933-8402 • Fax: (952) 933-0307

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St. Jude Medical Europe, Inc.
Tel: +32 2 774 68 11
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P/N 750226 Rev B

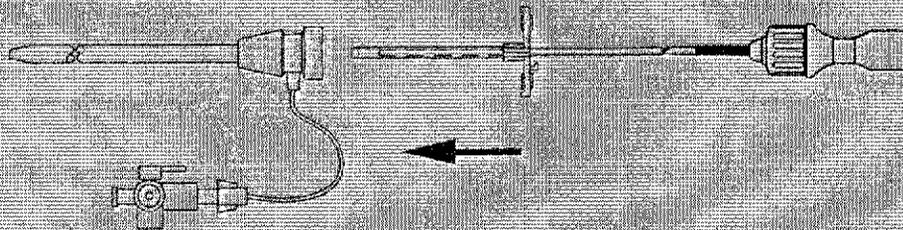
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Diagram / Diagrammet / Schematische tekening / Diagramme / Diagramm / Διάγραμμα / Figura / Diagrama / Diagrama / Diagrammet / Şekil / 图表

- English Slide the protective sheath over the distal loop section of catheter.
- Danish Før beskyttelseshylstret over den fjerne ende af katetret.
- Dutch Schuif de beschermende huls over het distale lusgedeelte van katheter.
- French Faites glisser la gaine de protection sur la boucle distale du cathéter.
- German Die Schutzhülle über den distalen Schlaufenabschnitt des Katheters schieben.
- Greek Ολισθήστε το προστατευτικό θηκάρι πάνω στο τμήμα του περιφερικού βρόχου του καθετήρα.
- Italian Far scorrere la guaina protettiva sulla sezione dell'anello distale del catetere.
- Portuguese Deslize a bainha de protecção sobre a secção do laço distal do cateter.
- Spanish Deslice la funda protectora por la parte del bucle distal del catéter.
- Swedish Glid skyddshylsan över den distala ögla del av katetern.
- Turkish Koruyucu kılıfı kateterin distal halka kısmının içinden kaydırın.
- Chinese 移动保护鞘管到导管顶端环状部分



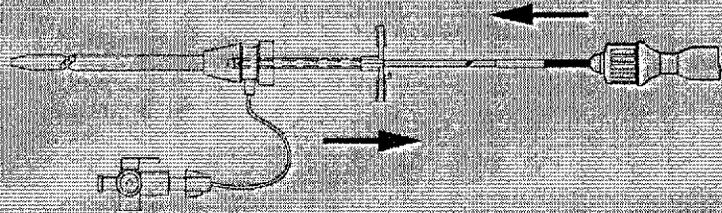
- English Insert the protective sheath with the catheter distal end into and through the hemostasis valve of the introducer (not included).
- Danish Indfør beskyttelseshylstret med den fjerne ende af katetret i og gennem den blodstansende klap på indførelsen (medfølger ikke).
- Dutch Steek de beschermende huls met de distale tip van de katheter in en door de hemostaseklep van de introducer (niet mbegrepen).
- French Insérez la gaine de protection placée sur l'électrode distale du cathéter à fond dans la valve hémostatique de l'introducteur (non fourni).
- German Die Schutzhülle mit dem distalen Ende des Katheters in und durch das Hemostase-Ventil des Introducer (Einführvorrichtung – nicht inbegriffen) hindurch einsetzen.
- Greek Πιράξτε το προστατευτικό θηκάρι με το περιφερικό άκρο του καθετήρα μέσα από την αιμοστατική βαλβίδα του εισαγωγέα (δεν περιλαμβάνεται).
- Italian inserire la guaina protettiva con l'estremità distale del catetere nella valvola emostatica dell'introduttore (non incluso).
- Portuguese Introduza a bainha de protecção com a extremidade distal do cateter em e através da válvula hemostática do introdutor (não incluído).
- Spanish Introduzca la funda protectora con el extremo distal del catéter dentro en la válvula de hemostasis del introductor (no incluido).
- Swedish För in skyddshylsan med kateterns distala ände genom introducerns hemostasventil (ingår ej).
- Turkish Koruyucu kılıfı kateter distal ucuya birlikte introducerin (dahil değildir) hemostaz vanasının içinden sokun.
- Chinese 将保护鞘连同导管顶端插入介入鞘（不包括在导管装置中）的止血阀中。



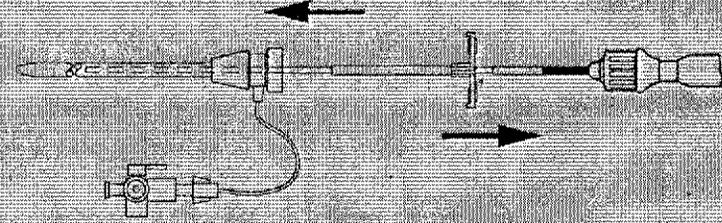
175

Diagram / Diagrammet / Schematische tekening / Diagramme / Diagramm / Διάγραμμα / Figura / Diagrama / Diagrama / Diagrammet / Şekil / 图表

- English Insert catheter through the hemostasis valve.
- Danish Før kateteret gennem den blodstandsende klap.
- Dutch Steek katheter door de hemostaseklep.
- French Insérez le cathéter dans la valve hémostatique.
- German Den Katheter durch das Hämostase-Ventil einsetzen.
- Greek Πιέστε τον καθετήρα από την αιμοστατική βαλβίδα.
- Italian Inserire il catetere nella valvola emostatica.
- Portuguese Introduza o cateter através da válvula hemostática.
- Spanish Introduzca el catéter en la válvula de hemostasis.
- Swedish För in katetern genom hemostasventilen.
- Turkish Kateteri hemostaz vanasından sokun.
- Chinese 导管送入介入鞘后。



- English After the catheter is inside the introducer, pull the protective sheath out from the hemostasis valve. Re-insert the protective sheath into the hemostasis valve prior to removing the catheter from the introducer.
- Danish Når kateteret er inde i introduceren, trækkes beskyttelseshylsret ud fra den blodstandsende klap. Indsæt atter beskyttelseshylsret i den blodstandsende klap, før kateteret fjernes fra introduceren.
- Dutch Wanneer de katheter in de introducer is, trek dan de beschermende huls uit de hemostaseklep. Steek de beschermende huls weer in de hemostaseklep voordat u de kateter uit de introducer verwijdert.
- French Une fois le cathéter à l'intérieur de l'introducteur, retirez la gaine de protection de la valve hémostatique. Réinsérez la gaine de protection dans la valve hémostatique avant de retirer le cathéter de l'introducteur.
- German Nachdem der Katheter innerhalb des Introducer platziert ist, ziehen Sie die Schutzhülle aus dem Hämostase-Ventil heraus. Setzen Sie die Schutzhülle wieder in das Hämostase-Ventil ein, bevor Sie den Katheter aus dem Introducer entfernen.
- Greek Αφού βρεθεί ο καθετήρας μέσα στον εισαγωγέα, τραβήξτε το προστατευτικό θηκάρι έξω από την αιμοστατική βαλβίδα. Εισάγετε πάλι το προστατευτικό θηκάρι στην αιμοστατική βαλβίδα πριν αφαιρέσετε τον καθετήρα από τον εισαγωγέα.
- Italian Dopo aver collocato il catetere nell'introdotore, estrarre la guaina protettiva dalla valvola emostatica. Prima di estrarre il catetere dall'introdotore, inserire nuovamente la guaina protettiva nella valvola emostatica.
- Portuguese Após o cateter estar dentro do introdutor, puxe a bainha de protecção da válvula hemostática. Volte a introduzir a bainha de protecção na válvula hemostática antes de remover o cateter do introdutor.
- Spanish Una vez colocado el catéter dentro del introductor, saque la funda protectora de la válvula de hemostasis. Antes de sacar el catéter del introductor, introduzca de nuevo la funda protectora en la válvula de hemostasis.
- Swedish Dra ut skyddshylsan ut hemostasventilen när katetern befinner sig inuti introducern. Sätt tillbaka skyddshylsan i hemostasventilen innan du tar ut katetern från introducern.
- Turkish Kateteri introduserin içine girdikten sonra koruyucu kilifi hemostaz vanasından çekin. Kateteri introduserden çıkarmadan önce koruyucu kilifi tekrar hemostaz vanasına yerleştirin.
- Chinese 将保护鞘拉出止血阀。在将导管从介入鞘中拉出之前，须先将保护鞘送入止血阀。



IBI INQUIRY™ OPTIMA™ STEERABLE DIAGNOSTIC CATHETER

English

CAUTION:

- United States law restricts this device to sale by or on order of a physician.
- Read directions prior to use.

DESCRIPTION:

The IBI Inquiry™ Optima™ steerable electrophysiology catheter incorporates both a distal end with a variable loop diameter, which allows selection of diameters within a specific range, and a deflatable shaft steering mechanism. The diameter of the distal loop may be contracted or expanded by turning the rotating knob. The distal shaft may be deflected by pushing and pulling the thumb control.

INDICATIONS FOR USE:

The Inquiry™ Optima™ Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiologic studies. The Optima™ catheters are to be used to map the atrial regions of the heart.

CONTRAINDICATIONS:

- The device is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via transeptal approach.
- This device should not be used via retrograde approach.
- This device is not intended for use in the ventricles.
- The device is not intended for transcatheter ablation.

DIRECTIONS:

1. Inspect the package prior to use. Do not use if the package is open or damaged.
2. Remove the catheter from its package. Inspect the electrodes and catheter carefully for integrity and overall condition.
3. See diagram for instruction on how to insert the distal tip section of the Optima™ catheter into the introducer using the protective sheath.
Note: Pull the thumb control downward completely and turn the rotating knob counter clockwise fully.
4. The catheter should be passed from a peripheral vessel to the desired endocardial position with the aid of fluoroscopy.
5. The catheter has a cable adapter and must be used with the appropriate cable. Refer to the cable instructions for details.
6. To record intracardiac electrograms, connect a patient cable to the Optima™ catheter.
7. Observe the polarity of the proximal end connector pins of the patient cable when connecting to an EP monitoring system.
8. Use care to isolate any unused connector pins. This will reduce the chances of developing accidental current pathways to the heart.
9. To adjust the distal loop diameter of the catheter, turn the rotating knob clockwise. To deflect the distal shaft of the catheter, push the thumb control located on the handle.
10. Always use fluoroscopy when manipulating the tip of the catheter.
11. To remove through the introducer, be sure to turn the rotating knob counter clockwise fully and pull the thumb control downward completely to make the loop larger and to straighten shaft of catheter before removal from introducer.
12. Do not resterilize and reuse.

WARNINGS:

- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of transvenous electrophysiology studies.
- Cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must therefore be given for the use of this catheter in pregnant women.
- Vascular perforation is an inherent risk of any electrode placement. Do not force the catheter through the vessel.
- Do not immerse the proximal handle or cable connector in fluids, electrical performance could be affected.
- This device is intended for one time use only.

PRECAUTIONS:

- Personnel handling the electrophysiology catheter should wear gloves.
- To maintain optimal patient safety and electrode catheter integrity, do not wipe this catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter.
- Standard grounding procedures should be followed if electrosurgical instruments are used.

CONNECTION TO OTHER EQUIPMENT:

This device may be connected to a commercially available EP recording system using a connection cable with redel connector in the pin configuration corresponding to this catheter. EP recording system must be "patient isolated," or have an isolated patient cable.

PACKAGING AND SHELF-LIFE:

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the products remain in the unopened package until time of use. Contents are sterile if the package is unopened and undamaged. Do not resterilize. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location.

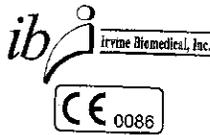
WARRANTY:

Irvine Biomedical, Inc. (IBI) warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products is set forth in the related "Instructions for Use" that accompany each product. IBI disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. IBI's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. IBI disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. IBI neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete IBI warranty policy available from IBI (1-949-851-2053) or on the back of an IBI invoice.

P/N 75226 Rev B

Page 4 of 16

English	Sterilized with Ethylene Oxide Gas	Read directions prior to use	This product is single use only, do not reuse or re-sterilize	Lot no	Use by	Item no	Manufacturer	European Authorized Representative	Recommended Cable
Danish	Steriliseret med ethylenoxidgas	Læs brugsanvisningen før brug	Dette produkt er kun til engangsbrug. Må ikke genbruges eller gensteriliseres	Parti nr.	Anvendes inden	Varenr.	Producent	Europæisk autoriseret repræsentant	Anbefalet ledning
Dutch	Gesteriliseerd ethylenoxidegas	Lees voor het gebruik de instructies	Dit product is bestemd voor eenmalig gebruik. Niet opnieuw gebruiken of steriliseren	Batchnr.	Gebruik door	Artikelnr.	Fabrikant	Gevolmachtigd vertegenwoordiger voor Europa	Aanbevolen kabel
French	Sterilisé au gaz d'oxyde d'éthylène	Lisez attentivement les instructions avant toute utilisation	Ce produit est à usage unique, ne le réalisez pas, ne le restérilisez pas.	N° de lot	Date de péremption	N° d'article	Fabricant	Représentant agréé en Europe	Câble recommandé
German	Mit Ethylenoxidgas sterilisiert	Vor der Verwendung die Gebrauchsanweisungen durchlesen	Dieses Gerät ist nur zum einmaligen Gebrauch bestimmt, nicht wiederverwenden oder erneut sterilisieren	Charge-Nr.	Verwenden bis zum	Artikel-Nr.	Hersteller	Autorisierter europäischer Vertreter	Empfohlenes Kabel
Greek	Ασπορτιζομένο με αέριο οξυγόνο αιθυλένιο	Διαβάστε τις οδηγίες πριν από τη χρήση	Η συσκευή αποστειρώνεται για χρήση εφάπαξ. Μην επαναποστερίσετε ή επαναχρησιμοποιήσετε τη συσκευή	Αριθμός-αποτίθεσης	Χρησιμοποιήστε μέχρι	Αριθμός άρθρου	Κατασκευαστής	Εξουσιοδοτημένος αντιπρόσωπος για την Ευρώπη	Επισημασμένο καλώδιο
Italian	Sterilizzato con ossido di etilene	Leggere le istruzioni prima dell'uso	Prodotto monouso non riutilizzare né sterilizzare nuovamente	Lotto n°	Data di scadenza	Numero di indice del prodotto	Casa produttrice	Rappresentante autorizzato per l'Europa	Cavo consigliato
Portuguese	Esterilizado com gás de Oxido de Etileno (EtO)	Leia as instruções antes da utilização	Este produto destina-se a ser utilizado uma única vez. Não reutilizar nem reesterilizar	N.º de lote	Prazo de validade	N.º de artigo	Fabricante	Representante Autorizado na Europa	Cabo Recomendado
Spanish	Esterilizado con gas óxido de etileno	Lea las instrucciones antes de utilizarlo	Este producto es de un solo uso. No lo vuelva a utilizar ni a esterilizar	Lot nº	Use por	Artículo nº	Fabricante	Representante europeo autorizado	Cable recomendado
Swedish	Steriliserad med etylenoxid	Läs bruksanvisningen före användning	Denna produkt är endast avsedd för engångsbruk inte för återanvändning eller omsterilisering	Partinr.	Använd före	Komponentnr.	Tillverkare	Autoriserad representant i Europa	Rekommenderad ledning
Turkish	Etilen Oksit Gazıyla Sterilize Edilmiştir	Kullanmadan önce talimatı okuyun	Bu ürün sadece tek kullanımlıktır, tekrar kullanılmayın ve sterilize etmeyin	Lot no	Son kullanma tarihi	Madde no	Çetirci	Yetkili Avrupa Temsilcisi	Önerilen kablo
Chinese	经环氧乙烷消毒	使用前请先阅读使用指导	此产品仅限一次性使用	批号	有效期	项目编号	制造商	欧洲授权代表	推荐使用的电缆



Inquiry Optima(TM)

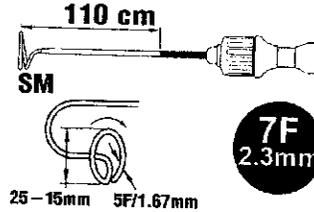
Diagnostic Catheter
 Diagnostický katetr
 Dianosa kateter
 Diagnostische katheter
 Diagnostic Cathéter

Diagnostik Katheter
 Διαγνωστικός καθετήρας
 Diagnostica Cateters
 Cewník do diagnozy
 Cateter para diagnóstico

Diagnóstico Catéter
 Diagnostisk kateter
 Tanisai kateter
 电生理诊断导管
 진단상의 도뇨관

REF 81683 LOT 38191 Use by: 2008/10
 1120-7-1(4.5)-SM-OPT25

20	1(4.5) mm
Electrodes / Elektrody / Elektroder / Elektrodes / Electrodes / Elektroden / Ηλεκτρόδια / Elettrodi / Elektrody / Electrodes / Electrodes / Elektroder / Elektroliar / 电极数 / 전극	Spacing / Rozteč / Afstandstykke / Abstand / Espacement / Abstand / Διαχωρισμός / Espaciamento / Odstepy / Espaçamento / Spaziatura / Avstånd / Aralık / 电极间距 / 간격



Irvine Biomedical, Inc.
 Phone: 949-851-3053, www.ibip.com

 M245818880E

REF 81683 LOT 38191
 1120-7-1(4.5)-SM-OPT25

 S5801100888191E1

Irvine Biomedical, Inc.
 Phone: 949-851-3053, www.ibip.com

 M245818880E

REF 81683 LOT 38191
 1120-7-1(4.5)-SM-OPT25

 S5801100888191E1

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

Non-Pyrogenic

Inquiry
 Optima(TM)

Electrodes: 20
 Spacing: 1(4.5) mm



7F
 2.3mm

IBI 1924
 Recommended Cable

REF 81683
 LOT 38191

Use by: 2008/10

1120-7-1(4.5)-SM-OPT25

Irvine Biomedical, Inc.

P/N 750224 Rev C

2375 Morse Avenue, Irvine California 92614 U.S.A. Phone: (949) 851-3053 * Toll Free: (888) IBI-9876

English	Contents: One (1) sterile electrophysiology catheter. Contents are sterile unless inner package is opened or damaged.	The product should be stored in a cool and dry location	Made in U.S.A
Czech	Obsah: Jeden (1) sterilní elektrofyziologický kabel. Obsah je sterilní, pokud není vnitřní obal otevřen nebo poškozen.	Výrobek nutno skladovat na chladném a suchém místě.	Vyrobeno v USA.
Danish	Indhold: Et (1) steril elektro-fysiologisk kateter. Indholdet er steril med mindre den inderste pakke er åbnet eller ødelagt.	Produktet bør opbevares i tørre og kølige omgivelser.	Fremstillet i USA
Dutch	Inhoud: Eén (1) steriele elektrofyziologiekatheter. Inhoud is steril tenzij de individuele verpakking geopend of beschadigd is.	Het product dient te worden opgeslagen in een droge en koele locatie.	Geproduceerd in de Verenigde Staten
French	Contenu : Un (1) cathéter électrophysiologie stérile. Le contenu est stérile sauf si l'emballage intérieur est ouvert ou endommagé.	Le produit doit être conservé dans un endroit frais et sec.	Fabriqué aux États-Unis d'Amérique
German	Inhalt: Ein (1) steriler Elektrophysiologie-Katheter. Der Packungsinhalt ist steril, falls die innere Verpackung ungeöffnet und unbeschädigt ist.	Das Produkt muss an einem kühlen, trockenen Ort aufbewahrt werden.	Hergestellt in den Vereinigten Staaten von Amerika.
Greek	Περιεχόμενο: Ένας (1) αποστειρωμένος καθετήρας ηλεκτροφυσιολογίας. Αποστειρωμένο περιεχόμενο εφόσον η εσωτερική συσκευασία δεν είναι ανοιγμένη ούτε καταστραμμένη.	Το προϊόν πρέπει να αποθηκεύεται σε χώρο δροσερό και στεγνό.	Κατασκευάστηκε στις ΗΠΑ
Italian	Contenuto: Catetere uno (1) sterile per elettrofisiologia. Il prodotto rimane sterile se la confezione e' sigilata e intatta.	Conservare il prodotto in un luogo fresco e asciutto	Fabbricato negli Stati Uniti d'America
Polish	Zawartość: Jeden (1) sterylony cewnik do badania elektrofizjologicznego. Zawartość jest sterylna jeżeli wewnętrzne opakowanie nie jest otwarte lub uszkodzone	Ten produkt powinien być magazynowany w chłodnych i suchych warunkach.	Wyprodukowano w U.S.A
Portuguese	Contém: 1 (um) cateter estéril para eletrofisiologia. O conteúdo encontra-se esterilizado, a menos que o pacote esteja aberto ou danificado.	O produto deve ser armazenado em um local fresco e seco.	Produto dos E.U.A.
Spanish	Contenido: Un (1) catéter de electrofisiología estéril. El contenido esta estéril si el embalaje no ha sido abierto o dañado.	Este producto debe almacenarse en un lugar fresco y seco.	Fabricado en los Estados Unidos de América
Swedish	Innehåll: En (1) steril elektrofysiologikateter. Innehållet är steril under förutsättning att den yttre förpackningen är öppnad och oskadad.	Produkten skall förvaras svalt och torr.	Tillverkad i USA
Turkish	İçindekiler: Bir (1) steril elektrofizyoloji kateteri. İçindekiler iç paket açık veya hasarlı değilse sterilidir.	Ürün serin ve kuru bir yerde saklanmalıdır.	A.B.D.'de üretilmiştir
Chinese	內含物: 一根无菌的 electrophysiology catheter. 內含物是无菌的, 除非内部的包装被打开或损坏.	本产品必须保存在凉爽干燥的地方	美国制造
Korean	내용물: 무균 전기생리학 도뇨관(導尿管) 한개 (1). 내부 패키지가 열렸거나 손상을 입지 않은 내용물은 무균상태임.	이 제품은 시원하고 건조한 장소에 보관해야 함.	미국 제품

Sterilized with Ethylene Oxide Gas.
本产品经环氧乙烷消毒

STERILE EO

Read directions prior to use.
在使用之前, 请参阅使用说明书



This product is single use only; do not reuse or resterilize.
此产品只供一次性使用, 不能消毒再用。



Manufacturer
Irvine Biomedical, Inc.
2375 Morse Avenue
Irvine, CA 92614 U.S.A
Tel: (949) 851-3053
Fax: (949) 851-3062

US Customer Service:
St. Jude Medical, Inc.
USA: (800) 253-9073
In MN Tel: (952) 933-8402 • Fax: (952) 933-0307

EC REP European Authorized Representative:
St. Jude Medical Europe, Inc.
The Corporate Village
Figueras Building
Avenue Da Vinclaan, 11, Box F1
1935 - Zaventem Belgium

EMEA Customer Services:
St. Jude Medical Europe, Inc.
Tel: +32 2 774 68 11
Fax: +32 2 772 83 84

REFLEXION SPIRAL™

Variable Radius Catheter

Bi-Directional Variable Radius Mapping Catheter

Instructions for use

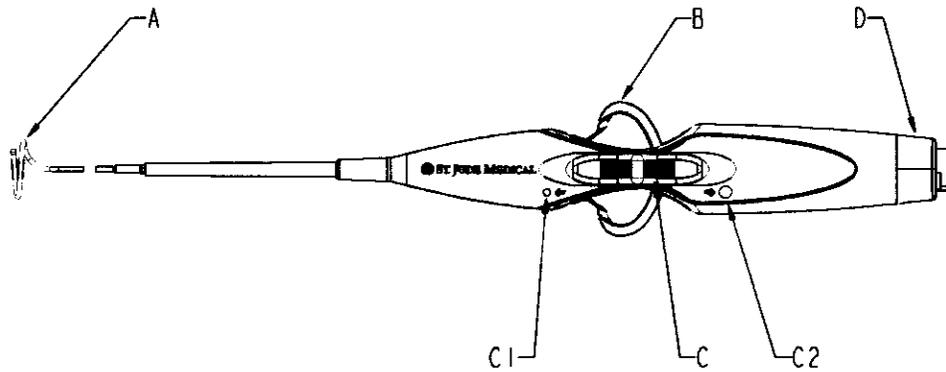


Figure 1.



See product catalog for reorder numbers and product description.

See individual sterile package label for contents.

Contents are sterile if package is unopened and undamaged.

DESCRIPTION

The St. Jude Medical (SJM) Reflexion Spiral™ Bi-Directional Variable Radius Mapping Catheter (Reflexion Spiral catheter) is a flexible, asymmetrical, bi-directional, variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates platinum electrodes.

Refer to Figure 1: The Reflexion Spiral catheter has a loop (A) and a proximal handle (the ComfortGrip™ handle) that contains: (B) A shaft actuator mechanism for varying the asymmetrical sweep (90° sweep) and curl (180° curl) of the distal portion of the shaft; (C) A loop actuator mechanism for varying the loop radius from approximately 25 mm (see C2) to approximately 15 mm (see C1); and (D) An electrical connector.

INDICATIONS FOR USE

The Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

CONTRAINDICATIONS

- This device is contraindicated for use as an ablation catheter.
- Electrophysiology studies are contraindicated when acute factors make the findings unrepresentative of the patient's usual state (i.e. electrolyte abnormality, acute ischemia, and drug toxicity).
- This device is contraindicated when the patient's underlying cardiac disease makes it likely that induced arrhythmias will be extremely difficult to terminate and carry a high risk of death (i.e., acute myocardial infarction, unstable angina, hemodynamic instability).
- This device is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch.

WARNINGS

- Single-use disposable medical device. Do not resterilize.
- Do not reuse this device. Thorough cleaning of biological and foreign material is impossible. Adverse patient reactions may result from reuse of this device.
- Vascular and/or cardiac perforation may occur during use. If resistance is observed, DO NOT FORCE CATHETER. Withdraw catheter, correct difficulty, and reinsert.
- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of interventional electrophysiology studies.
- To avoid potential damage to catheter or anatomical structures, always straighten deflectable shaft and open loop to largest diameter before insertion or withdrawal of catheter through a vascular introducer. Verify by using fluoroscopy and/or handle indicators.
- To maintain integrity of loop, use straightener provided when inserting catheter into introducer.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.

PRECAUTIONS

- Read Instructions for use prior to use of this device.
- Use only St. Jude Medical vascular introducers.
- Do not deflect loop or shaft while distal tip portion is in vascular introducer.
- Use with electrically isolated equipment.
- This device is not compatible with Magnetic Resonance Imaging (MRI) systems.
- Do not alter this device.
- Do not expose the catheter to organic solvents such as alcohol.
- Inspect all components prior to use.
- Not recommended for long term pacing.
- This device should only be used with equipment that complies with international safety standards.

- Proper electrical functioning of this device requires that the catheter be handled with care. Stretching and/or kinking while removing device from packaging, or cleaning of the catheter may result in damage.
- For specific details in the use of electrophysiology catheters and the techniques employed in an electrophysiology study, the physician should be referred to the medical literature and rely on training and practical experience.
- Store in a cool, dark, dry place.

RISK RELATED TO CARDIAC CATHETERIZATION

The risks of use of electrophysiology catheters include those risks related to cardiac catheterization in general, such as thromboembolism, cardiac perforation, tamponade, and infection. The induction of atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF) can be risks associated with electrical stimulation.

DIRECTIONS FOR USE

- Use a St. Jude Medical introducer with hemostasis valve to insert the Reflexion Spiral Catheter into the vascular system.
- Prior to insertion in patient, become thoroughly familiar with the operation of the handle controls.
 - To manipulate the distal shaft of the catheter, adjust the shaft actuator mechanism on either side of the handle (see B on Figure 1).
 - To adjust the spiral loop, adjust the loop actuator mechanism (see C on Figure 1) anywhere between a fully closed loop (C1) to a fully open loop (C2).
- Fully open the spiral loop of the catheter prior to insertion.
- Advance the tip straightener over the distal tip of the catheter prior to insertion into the hemostasis introducer.
- Insert tip straightener fully into hemostasis valve before advancing catheter into introducer.
- Never manipulate the spiral loop or deflectable section of the shaft while within the introducer.
- Always use fluoroscopy when positioning the catheter.
- To record intracardiac electrograms or perform stimulation, connect an SJM Response™ extension cable to the catheter.
- Connect cable to the catheter interface of the data acquisition system.
- Prior to removal, deflect catheter shaft to straight position and fully open the catheter spiral loop.

SYMBOL

SYMBOL DEFINITIONS



Bi-Directional Variable Radius Mapping Catheter



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



Reorder Number or Catalog Number



Batch code



Useable length of the device



Manufacturer

Manufacturer



Use by



Contents of the package



Inter-Electrode Spacing (mm)



Caution, consult accompanying documents



Protect from heat and radioactive sources



Keep dry



Do not reuse



Do not re-sterilize



Sterilized using ethylene oxide



Do not use if package is damaged

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LIMITED WARRANTY AND DISCLAIMER

St. Jude Medical (SJM) hereby warrants that if any SJM product fails to perform within normal tolerances for a patient due to a defect in material or workmanship, SJM will provide, at no charge, a replacement SJM 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 SJM.
2. The failed product must be returned to SJM and becomes the property of SJM.
3. The product has not been mishandled, reprocessed or altered in any way.
4. The product was used before the "USE BY" date marked on the packaging of the product.

No representation or warranty is made that a SJM product will not fail. SJM disclaims responsibility for any medical complications, including death, resulting from the use of its products. Except as expressly provided by this limited warranty, SJM 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, SJM MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.



Manufacturer
ST. JUDE MEDICAL
14901 DeVeau Place
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TEL: 800 328 3873
952 933 4700
FAX: 952 933 0307
www.sjm.com
Made in USA



St. Jude Medical Europe, Inc.
The Corporate Village
Avenue Da Vinci Laan, 11, Box F-1
B-1935 Zaventem
Belgium
TEL: 32 2 774 68 11
FAX: 32 2 772 83 84

41704 Rev. C
06/06

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 **ST. JUDE MEDICAL**

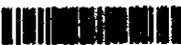
REFLEXION SPIRAL™ 
Variable Radius Catheter



REF 402804	LOT XXXXXXXX
LENGTH 99 cm	SPACING mm 1-4-1
 20XX-XX	CONTENTS 1 Catheter

7F | 20 | **SMLCURL** | **90° SWEEP**
(2mm Tip) 25-15 mm Variable Radius

U.S. Pat.: 5,861,084 and Patent(s) Pending.


7F
2mm Tip
**H80440280418*
REFLEXION SPIRAL CATHETER
25-15 mm Variable Radius
890130000800000000
USE BY: 20XX-XX LOT NO. XXXXXXXX

 **Manufacturer**
ST. JUDE MEDICAL
14901 DeVeau Place
Minnetonka, MN 55345-2126 USA
952-933-4700 800-328-3873
FAX: 952-933-0307
www.sjm.com

 **STERILE EO**

MADE IN USA 41703-000 Rev. B

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REFLEXION SPIRAL™ 
Variable Radius Catheter

7F
(2mm Tip)

20 | SML CURL | 90° SWEEP | 1-4-1
25-15 mm Variable Radius

REFLEXION SPIRAL™ 
Variable Radius Catheter



REF
402804

LOT
XXXXXXXX

LENGTH
99 cm

SPACING **mm**
1-4-1


20XX-XX

CONTENTS
1 Catheter

7F | 20 | SMLCURL | 90° SWEEP
(2mm Tip) 25-15 mm Variable Radius



+118844028042A



+938013XXXX28XXXXXXXA

USE BY: 20XX-XX LOT NO. XXXXXXXX


Manufacturer
ST. JUDE MEDICAL
14901 DeVeau Place
Minnetonka, MN 55345-2126 USA
952-933-4700 800-328-3873
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www.sjm.com

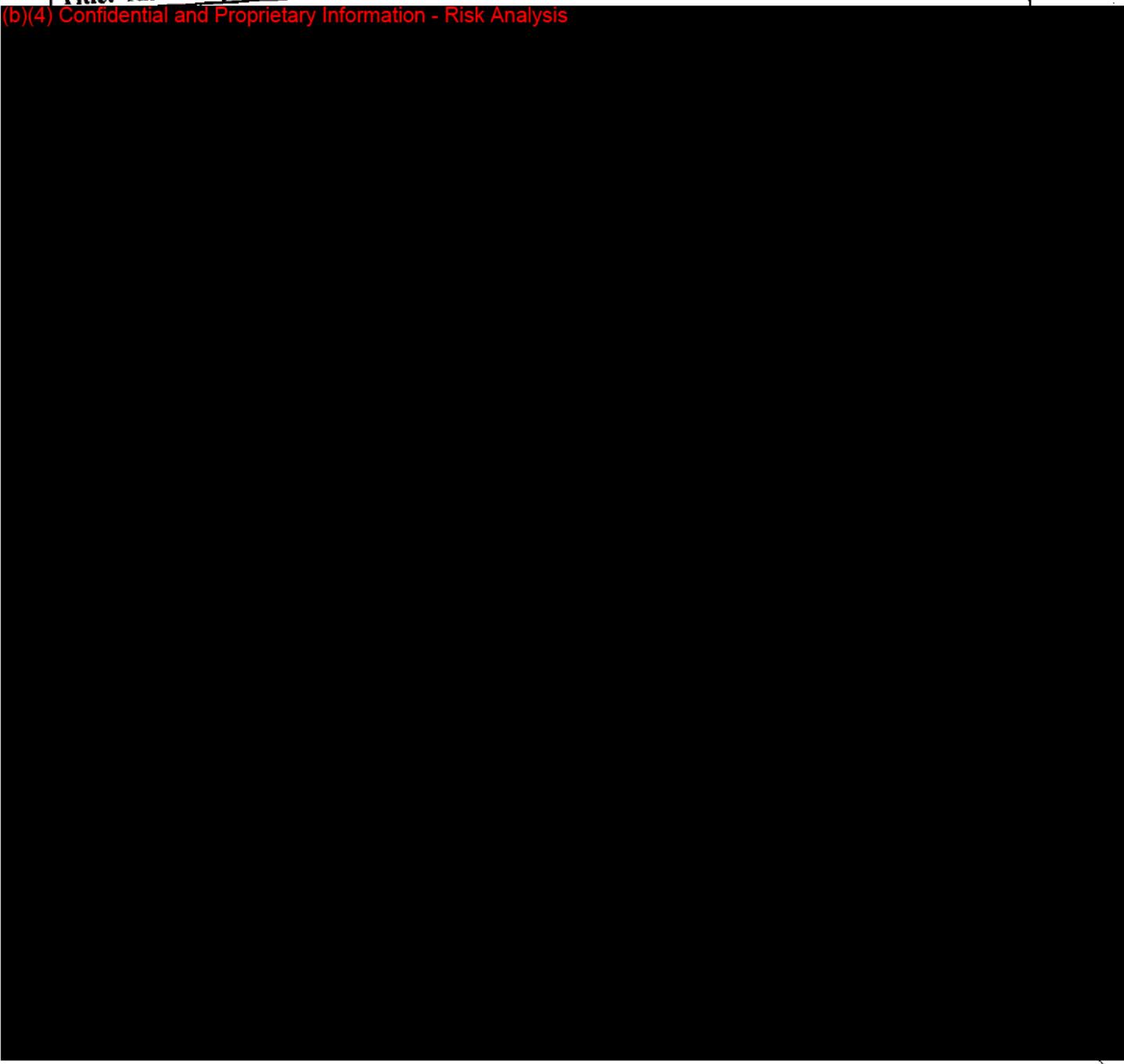
     

 **STERILE EO**

MADE IN USA 41702-000 Rev. B

 ST. JUDE MEDICAL RISK ANALYSIS	<p>(b)(4) Confidential and Proprietary</p> <p>R I S K</p> <p>Project No. (b)(4) Confidential</p> <p>Date: 13 June 2006</p> <p>Revision: 4</p> <p>Page: 1 of 129</p>
Title: Risk Analysis for Reflexion Spiral Steerable Diagnostic Catheter	

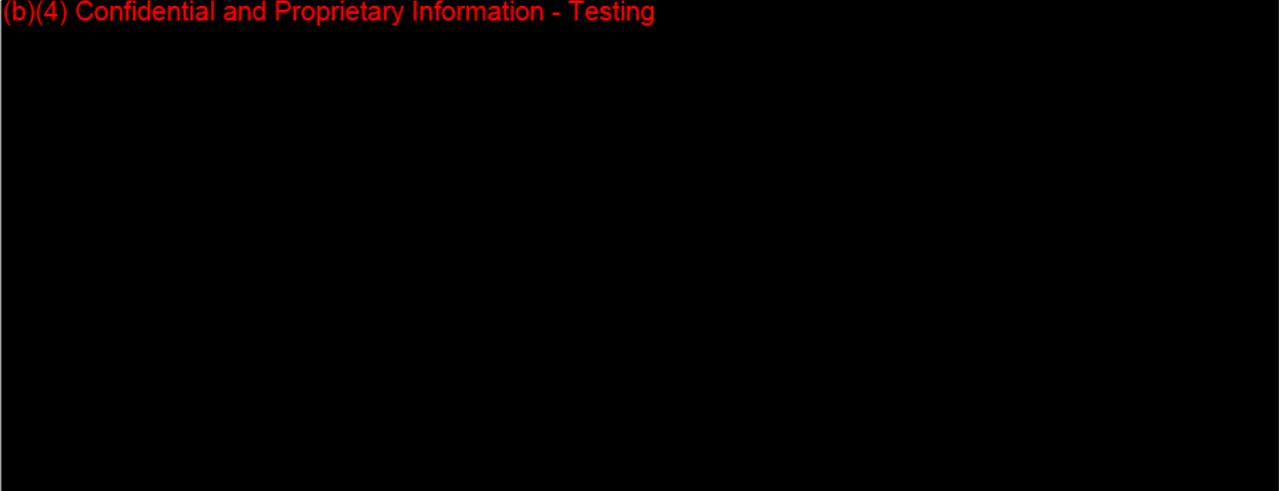
(b)(4) Confidential and Proprietary Information - Risk Analysis



 ST. JUDE MEDICAL REPORT	No. (b) (4) Project No. (b) (4) Date: July 26 th , 2006 Issue: 01 Page 1 of 74
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Title: Reflexion Spiral Duo-Decapolar Design Verification Testing Report

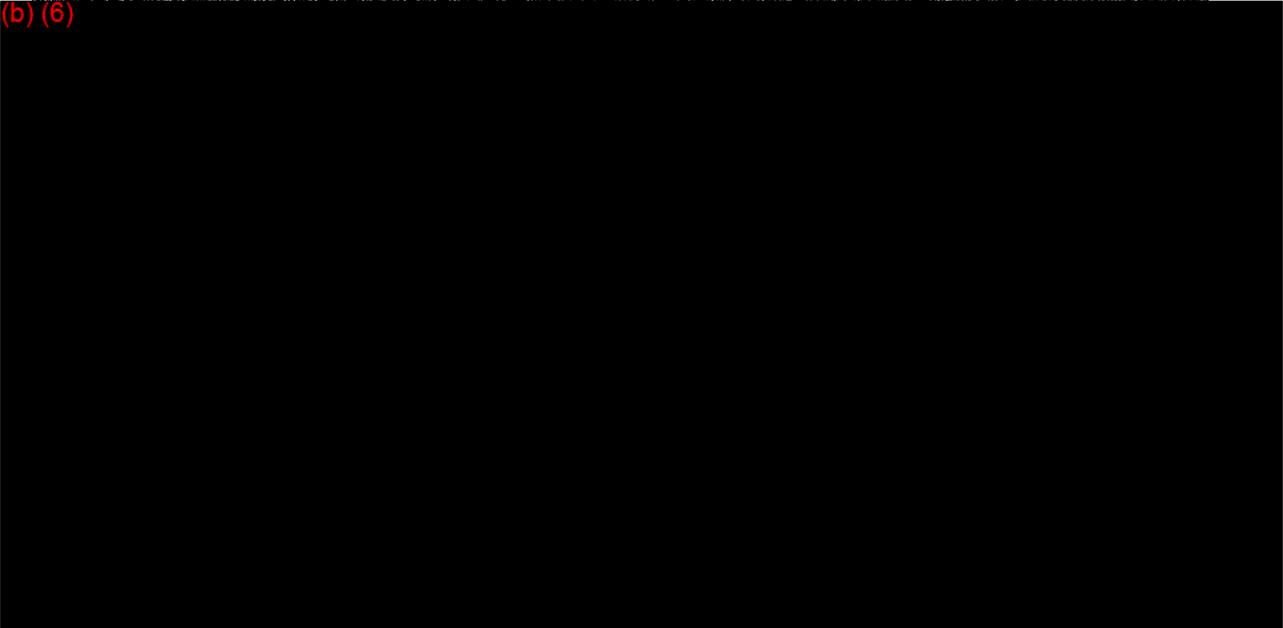
(b)(4) Confidential and Proprietary Information - Testing



Revision History: 01 – Create



(b) (6)



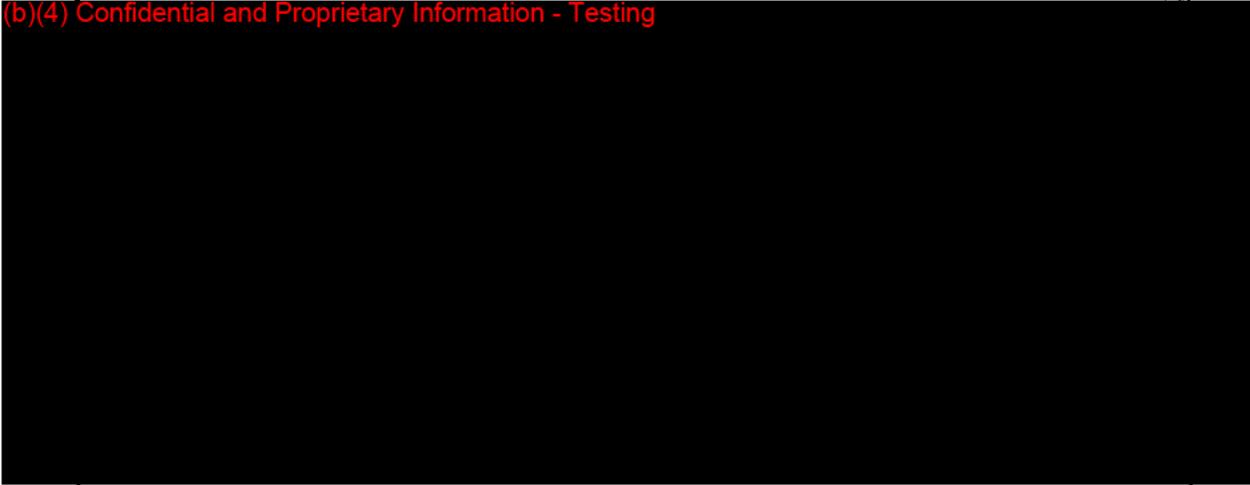
(b) (4)

Accelerated Aged Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter, Issue: 1

Page 1 of 83

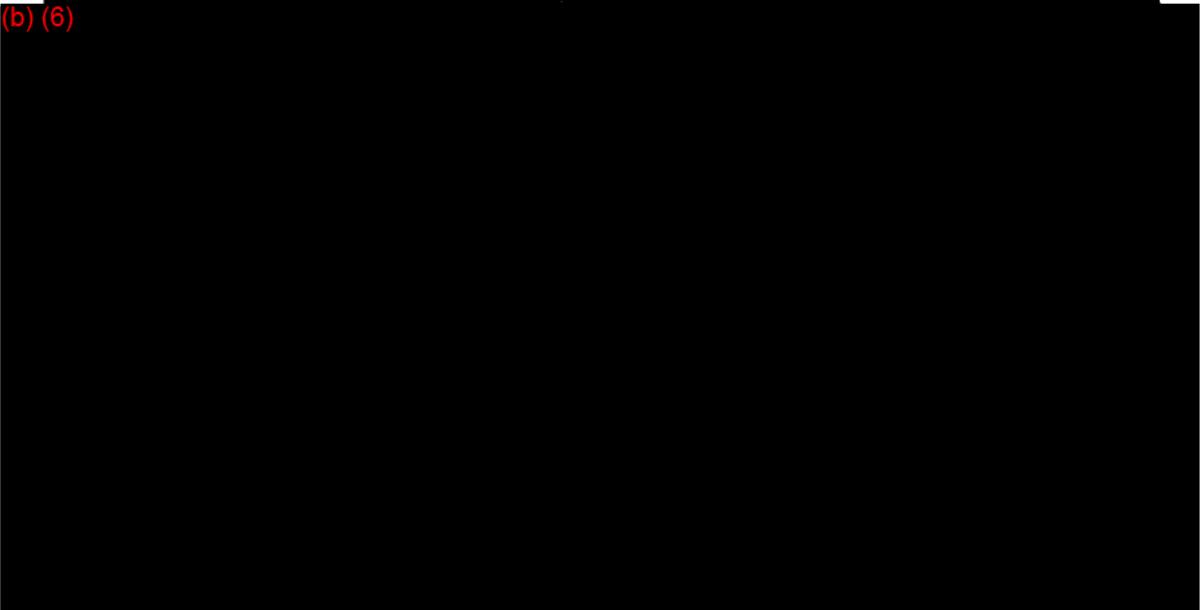
 ST. JUDE MEDICAL PROTOCOL	No. (b) (4) Project No. (b) (4) Date: July 28, 2006 Issue: 1 Page 1 of 83
Title: (b) (4) Accelerated Aged Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter	

(b)(4) Confidential and Proprietary Information - Testing



Revision History: 01 – Create

(b) (6)



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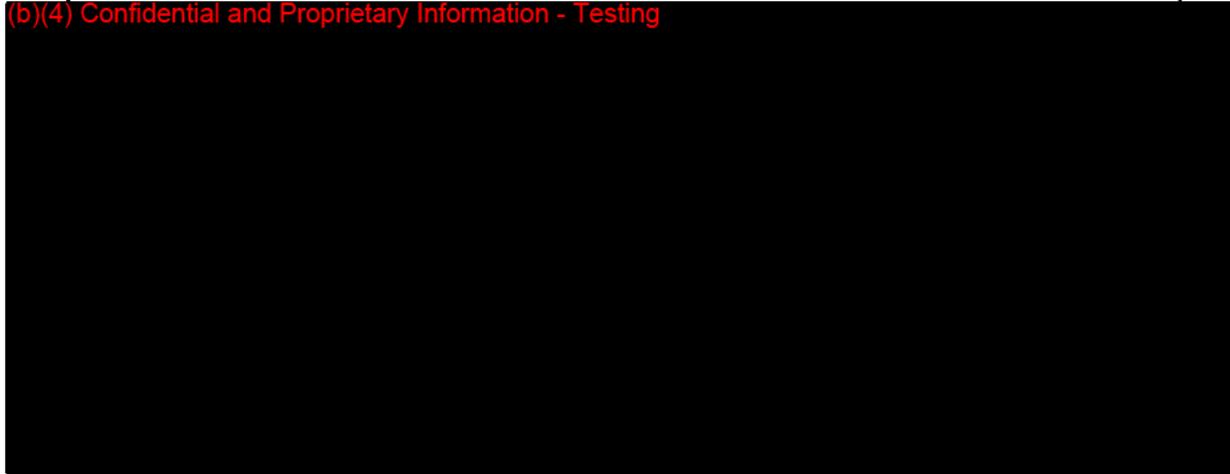
(b) (4)

Accelerated Aged Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter, Issue: 1

Page 1 of 83

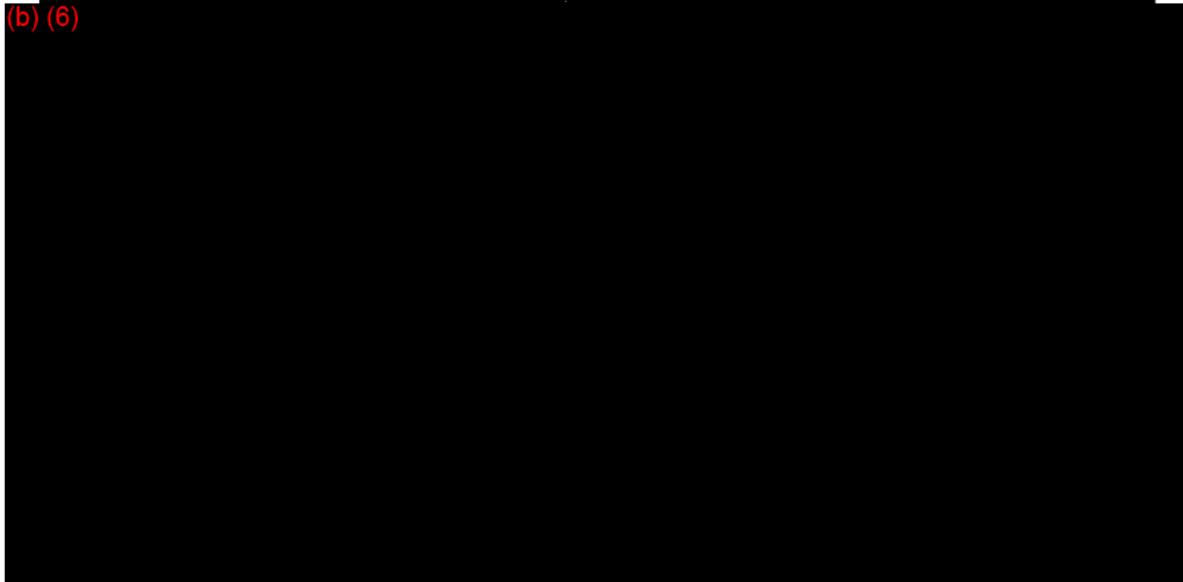
 ST. JUDE MEDICAL PROTOCOL	(b) (4) Date: July 28, 2006 Issue: 1 Page 1 of 83
Title: (b) (4) Accelerated Aged Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter	

(b)(4) Confidential and Proprietary Information - Testing



Revision History: 01 – Create

(b) (6)



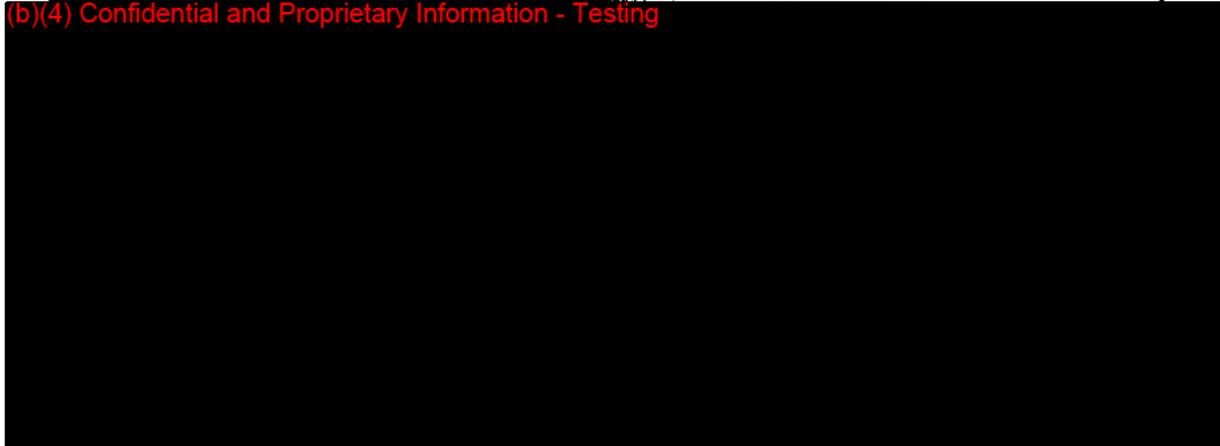
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Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter, Issue: 1

Page 1 of 82

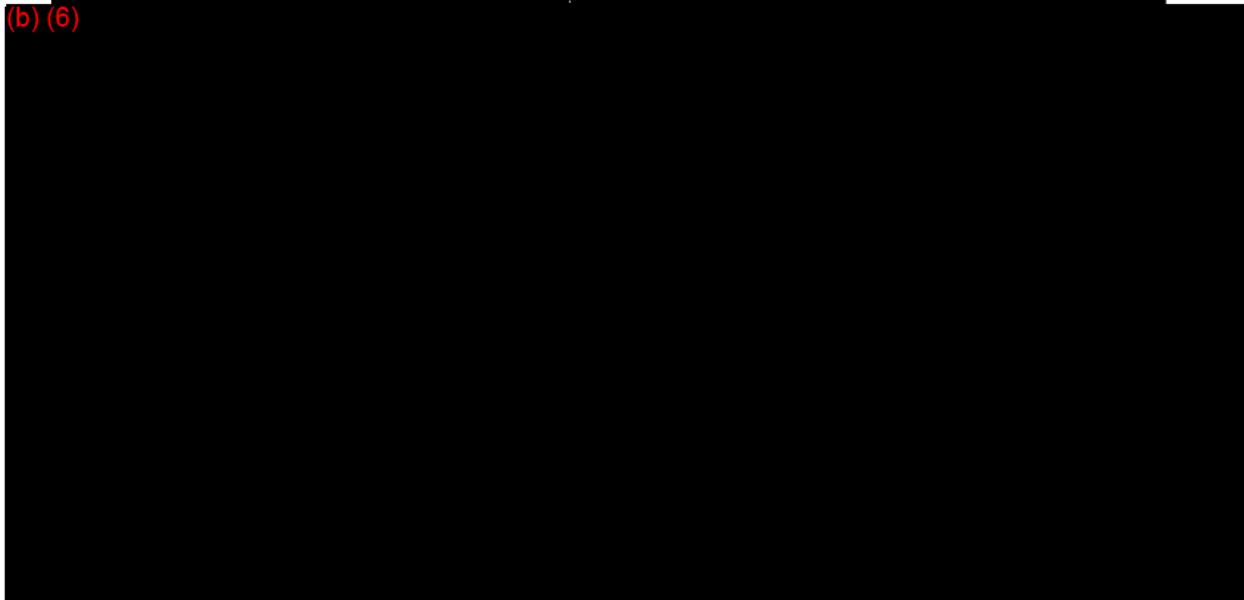
 ST. JUDE MEDICAL PROTOCOL	(b) (4) Date: July 28, 2006 Issue: 1 Page 1 of 82
Title: (b) (4) Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter	

(b)(4) Confidential and Proprietary Information - Testing



Revision History: 01 – Create

(b) (6)



(b) (4)

Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter, Issue: 1

Page 1 of 82

 **ST. JUDE MEDICAL**
PROTOCOL

(b) (4)

Date: July 28, 2006
Issue: 1
Page 1 of 82

Title: (b) (4) Shelf Life Testing of the Reflexion Spiral™ Diagnostic Catheter

(b)(4) Confidential and Proprietary Information - Testing

Revision History: 01 - Create

(b) (6)



~~PROTOCOL~~ *Report*
8/2/06

(b) (4)

Date: 08/01/2006

Issue: 01

Page: 1 of 14

Title: Biocompatibility Testing of the Reflexion Spiral EP Diagnostic Catheter

(b)(4) Confidential and Proprietary Information - Testing

Revision History:

01 - Create

Protocol Approvals:

(b) (6)

375

Title: Report 05-681 Biocompatibility Testing of the Reflexion Spiral EP Diagnostic Catheter

Appendix A

Lab Reports

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(b) (4)

FINAL STUDY REPORT

STUDY TITLE

ISO MEM Elution (b)(4) Confidential and Proprietary Information - Testing

TEST ARTICLE IDENTIFICATION

Reflexion Spiral Diagnostic Catheter, (b) (4)
Lot Number: (b) (4)

STUDY COMPLETION DATE

July 26, 2006

PERFORMING LABORATORY

(b) (4)

SPONSOR

St. Jude Medical, Inc.
Atrial Fibrillation Division 14901 DeVeau Place
Minnetonka, MN 55345-2126

PROTOCOL NUMBER

(b) (4)

PROJECT NUMBER

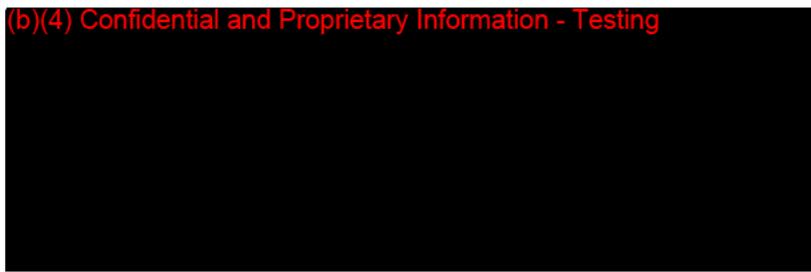
(b) (4)

(b) (4)

390

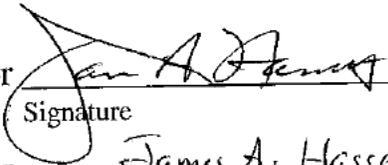
PRECLINICAL EVALUATION OF THE REFLEXION™ SPIRAL™ DUO-DECAPOLAR DIAGNOSTIC CATHETER

(b)(4) Confidential and Proprietary Information - Testing



Sponsor: St. Jude Medical, Atrial Fibrillation Division
14901 DeVeau Place
Minnetonka, MN 55345

Office: 800-328-3873
Fax: 612-352-9752

Study Director		Date	<u>7/26/06</u>
	Signature		
Study Director	<u>James A. Hassett</u>		
	Printed		

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V. STUDY DIRECTOR	1
VI. PURPOSE OF STUDY.....	1
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PURPOSE	1
SPECIFIC OBJECTIVES.....	1
POTENTIAL BENEFIT TO THE LIFE SCIENCES	2
VII. CONTROL ARTICLES	2
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I. TITLE OF STUDY

Preclinical Evaluation of the Reflexion Spiral Duo-decapolar Diagnostic Catheter

II. COMPLIANCE WITH GOOD LABORATORY PRACTICES

The following written protocol was designed in accordance with Title 21, Code of Federal Regulations, Part 58, Subpart G, Section 58.120 concerning **Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies**. However, this study is not being conducted under GLP.

III. SPONSOR

St. Jude Medical, Atrial Fibrillation Division
14901 DeVeau Place
Minnetonka, Minnesota 55345

IV. TEST FACILITY

(b) (4)

V. STUDY DIRECTOR

James A. Hassett
Vice-president, Clinical Development
St. Jude Medical/Atrial Fibrillation Division

VI. PURPOSE OF STUDY

Background

The Reflexion Spiral is a circumferential mapping catheter with a braided shaft, bi-directionality, and variable radius capability. This diagnostic catheter is intended for use in electrical stimulation and sensing of the heart.

Purpose

The purpose of this study was to obtain testing data to ensure the device meets the indications for use of sensing and stimulation while also assessing human factors such as ease of use and attaining locations within the cardiac anatomy. Data derived from this study may be used to support market-clearance applications, e.g., 510(k) or CE Mark.

Specific Objectives

(b)(4) Confidential and Proprietary Information - Testing

1
4/6

Potential benefit to the life sciences

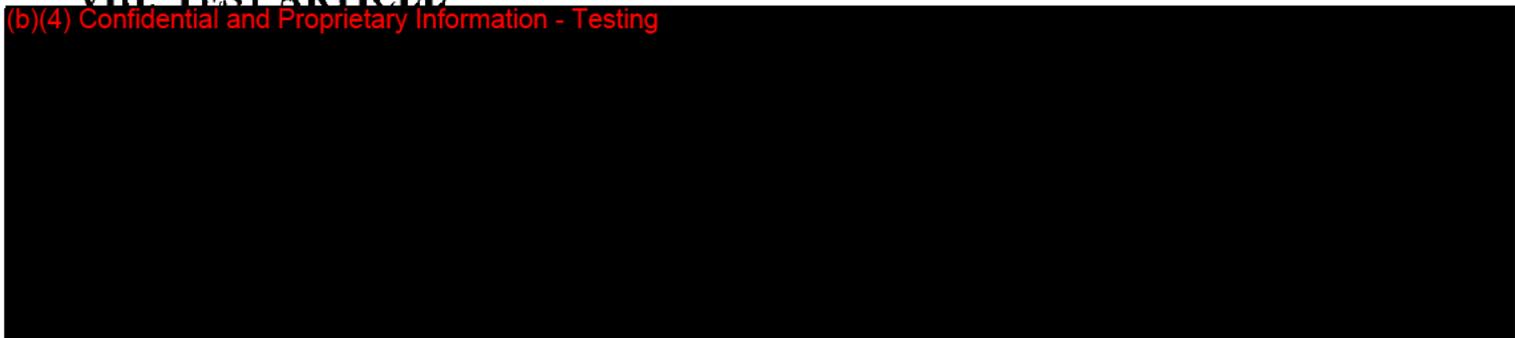
It is the hypotheses of this study that electrophysiological mapping and stimulation can be performed efficiently and effectively with the Reflexion Spiral catheter. After validation, physicians will be able to apply this device in the clinical setting to perform diagnostic electrophysiologic evaluations. Therefore, the use of animals in this study is justified to accomplish the goals set forth.

VII. CONTROL ARTICLES

There is no control test article associated with this study.

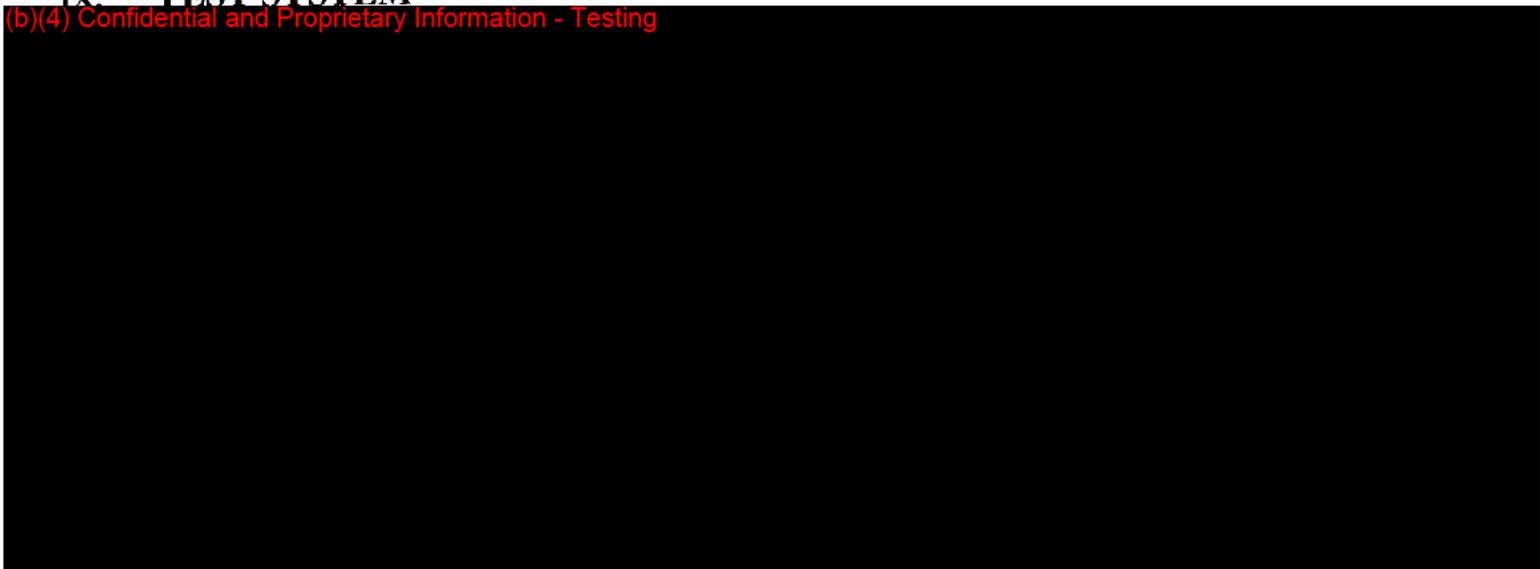
VIII. TEST ARTICLE

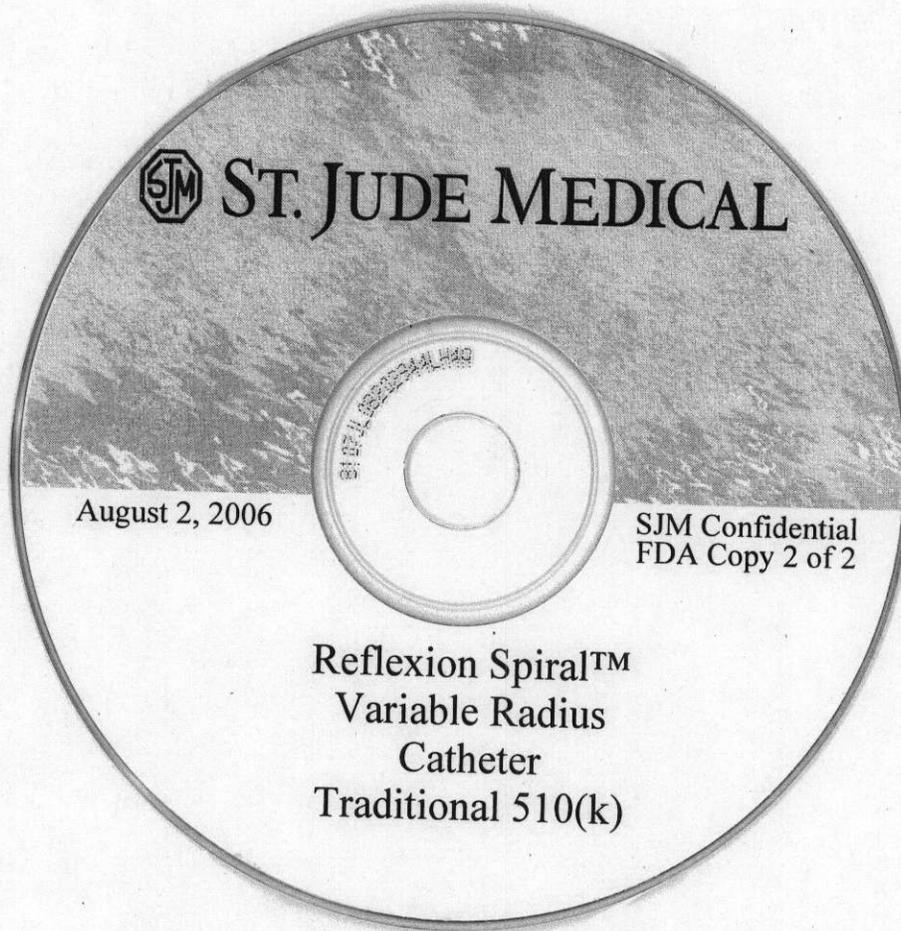
(b)(4) Confidential and Proprietary Information - Testing



IX. TEST SYSTEM

(b)(4) Confidential and Proprietary Information - Testing







DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Memorandum

From: Felipe Aguel

Subject: K062251

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.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is the device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k) YES NO
- Abbreviated 510(k) YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed

A 510(k) summary OR A 510(k) statement

~~The required certification and summary for class III devices~~ N/A

The Indication for Use form

~~Combination Product Category:~~ _____ N/A

Material of Biological Origin YES NO

~~Animal Source Material Human Tissue Product Human Cell Product Human Extraction Product N/A~~

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

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

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

74-DRF, class II (two) CFR 870.1220
(special controls) FA

Review: *[Signature]*
(Branch Chief)

CEMB
(Branch Code)

10/17/06
(Date)

Final Review: *[Signature]*
(Division Director)

12/19/06
(Date)

Revised: 6/5/98, 4/2/03, 10/7/03 FA

4

REVISED:3/14/95, 10/8/2003 FA

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

K062551

Reviewer: Felipe Aguel, Ph.D. *FA*

Division/Branch:DCD/CEMB

Device Name: Reflexion Spiral Variable Radius Catheter, Model 402804

Product To Which Compared (510(K) Number If Known): K042775

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

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.

6

1. Intended Use:
The Reflexion Spiral Catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiological studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.
The proposed device is a single use, sterile, flexible asymmetric, bidirectional, variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates 19 1mm ring and 1 distal 2mm tip platinum/iridium electrodes. The 20 electrodes are arranged in bipolar pairs with 1mm intra-pair spacing along the circumference of the distal loop which is oriented in the plane perpendicular to the long axis of the catheter shaft.
See review memo for further details.

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
Bench testing to demonstrate mechanical and electrical performance, biocompatibility testing, and sterility testing are needed to demonstrate substantial equivalence.
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

See attached review memo.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Memorandum

DATE: October 16, 2006

FROM: Felipe Aguel, Ph.D.
Biomedical Engineer
CDRH/ODE/DCD/CEMB, HFZ-450

SUBJECT: K062251 – **Traditional 510(k)**
Reflexion Spiral Variable Radius Catheter
St. Jude Medical
Atrial Fibrillation Division
14901 DeVeau Place
Minnetonka MN 55345

CONTACT: Glenn Jaques
Regulatory Affairs Manager

Tel: (952) 933-4700
Fax: (952) 930-9481
Email: gjaques@sjm.com

To: The Record

BACKGROUND

The sponsor, St. Jude Medical, has submitted an original premarket notification (510(k)) to seek market clearance for the Reflexion Spiral Variable Radius Catheter, Model Number 402804, and has identified this application as a **Traditional 510(k)** submission.

The predicate device cited is the Irvine Biomedical Inquiry Optima Steerable Electrophysiology Catheter manufactured by Irvine Biomedical cleared under 510(k) submission K042775.

This is my first review of this 510(k) application. Upon marketing clearance, the proposed device would be classified under 21 CFR §870.1220, as Class II with panel and product code of 74 DRF. *(special controls) PJ*

The submission was amended on October 4, 2006. The sponsor submitted the test results of the 1 year accelerated aging shelf life study. The original submission only included the protocol for the 1 year accelerated aging shelf life study.

INTENDED USE

As taken from the indications for use statement (section 4 of the submission), the Reflexion Spiral Catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiological studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.



Protecting and Promoting Public Health

The indications for use statement is different from that identified in submission K042775 in that the predicate device is intended for use during 'diagnostic' electrophysiology studies. I don't believe this is a significant change since all electrophysiology studies are diagnostic in nature, and the design of the catheter is clearly a mapping catheter.

SUMMARY

- | | | |
|---|---|--|
| Is the device life-supporting or life-sustaining? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device an implant (short-term or long-term)? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device sterile? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the device for single use? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the device for prescription use? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the device for home use or portable? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device a combination product? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device a kit? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is this device software driven? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| What is the estimated level of concern? | <input type="checkbox"/> Major | <input type="checkbox"/> Moderate <input type="checkbox"/> Minor |
| Is the device electrically operated? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |

STANDARDS REFERENCED

The following table summarizes the standards used in the performance testing of the proposed device.

Table 9.1 – Voluntary Standards

Quality System	<ul style="list-style-type: none"> • ISO 13485, Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001 • ISO 14971, Medical devices -- Application of risk management to medical devices
Biocompatibility	<ul style="list-style-type: none"> • ISO 10993-01: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
Sterilization and Pyrogenicity	<ul style="list-style-type: none"> • EN 550: Sterilization of Medical Devices – Validation and Routine Control of EtO Sterilization • EN 556: Sterilization of Medical Devices – Requirements for medical devices to be designated “STERILE” • ISO 10555: Sterile, single-use intravascular catheters • ISO 11135: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization • ISO 11138: Sterilization of health care products-Part 2:Biological indicators for ethylene oxide sterilization • ISO 11737: Sterilization of medical devices-Microbiological methods • ISO 14161: Sterilization of health care products-Biological indicators-Guidance for the selection, use and interpretation of results • FDA Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices, 1987.
Packaging	<ul style="list-style-type: none"> • ISO 11607, Packaging for Terminally Sterilized Medical Devices • ASTM F 1980-99, Standard Guide for Accelerated Aging of Sterile Medical Device Packages • ASTM D4169-05a, Simulated Distribution Testing
Product Specific	<ul style="list-style-type: none"> • ISO 10555-1, Sterile, Single-Use Intravascular Catheters Part 1: General Requirements • ASTM F640-79: Standard Test Methods for Radiopacity of Plastics for Medical Use

DEVICE DESCRIPTION

The St. Jude Medical Reflexion Spiral Variable Radius Catheter is a single use, sterile, flexible asymmetric, bidirectional, variable radius loop electrophysiology catheter (b) (4)

(b)(4) Confidential and Proprietary Information

The catheter contains a shaft actuator mechanism for varying the asymmetrical sweep (90°) and curl (180°) of the distal portion of the shaft. It also contains a loop actuator mechanism for varying the loop diameter from approximately 25mm to approximately 15mm. Finally, it contains an electrical connector on the proximal end of the handle. (b)(4) Confidential and Proprietary

(b)(4) Confidential and Proprietary Information

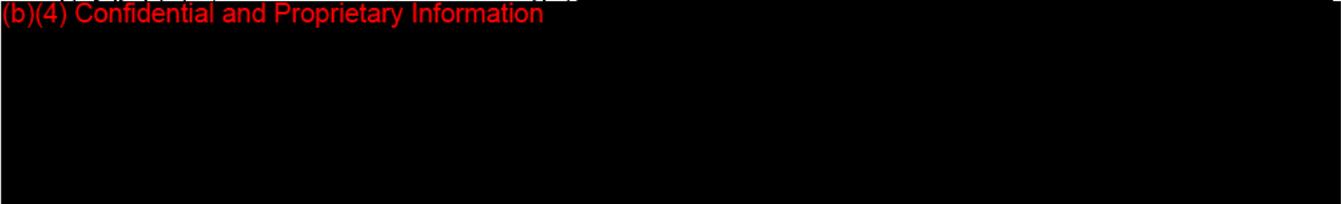
The catheter is inserted into the femoral artery and guided through a sheath into the left or right atrium using fluoroscopic imaging. The catheter is used to measure electrical potentials in the

atria which are then displayed on an ECG monitor. The catheter can also be used to deliver pacing stimuli to the atrial myocardial tissue.

SUBSTANTIAL EQUIVALENCE

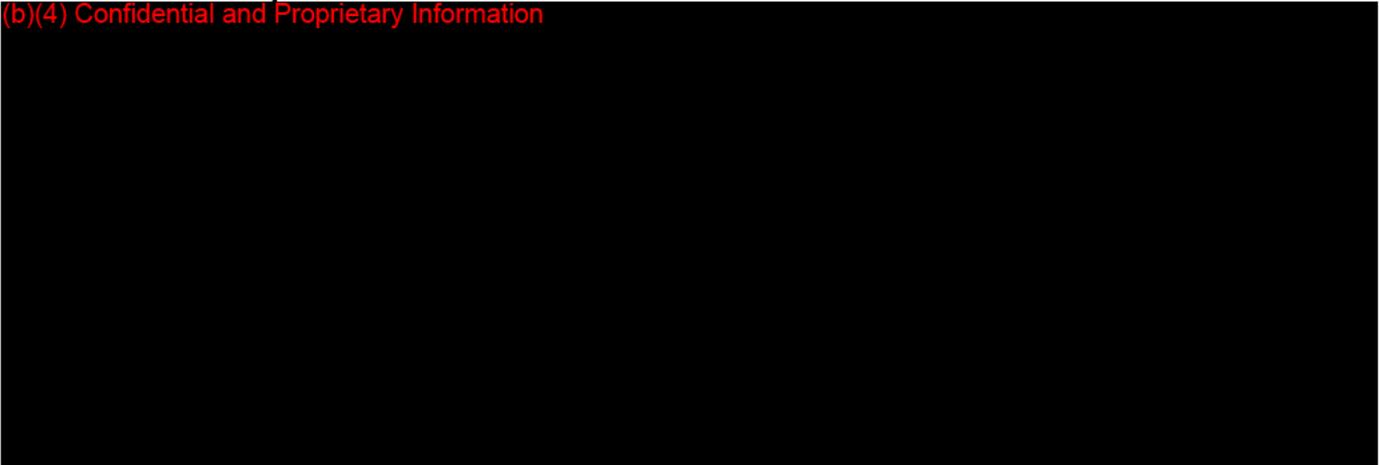
Comparison to predicate

The predicate device is a similar design: (b)(4) Confidential and Proprietary Information
(b)(4) Confidential and Proprietary Information



Predicate Comparison Table

(b)(4) Confidential and Proprietary Information



Property	Subject Device: Reflexion Spiral Catheter this 510(k)	Predicate Device Optima Catheter K042775
Device Characteristics	(b)(4) Confidential and Proprietary Information	
Catheter design		Uni-directional, variable radius circular mapping catheter
Outer diameter		7F w/5F distal loop
Guiding introducer compatibility		7F or larger
Electrodes		20 electrodes in 10 bipolar pairs 1 mm intra-pair spacing
Radiopaque markings		Catheter shaft and electrodes are radiopaque
Steerable		Yes
Deflection direction		Unidirectional
Usable lengths		180° Deflection 110cm
Loop diameter		Variable 25mm to 15mm diameter
Packaging		Dual barrier

(b)(4) Confidential and Proprietary Information

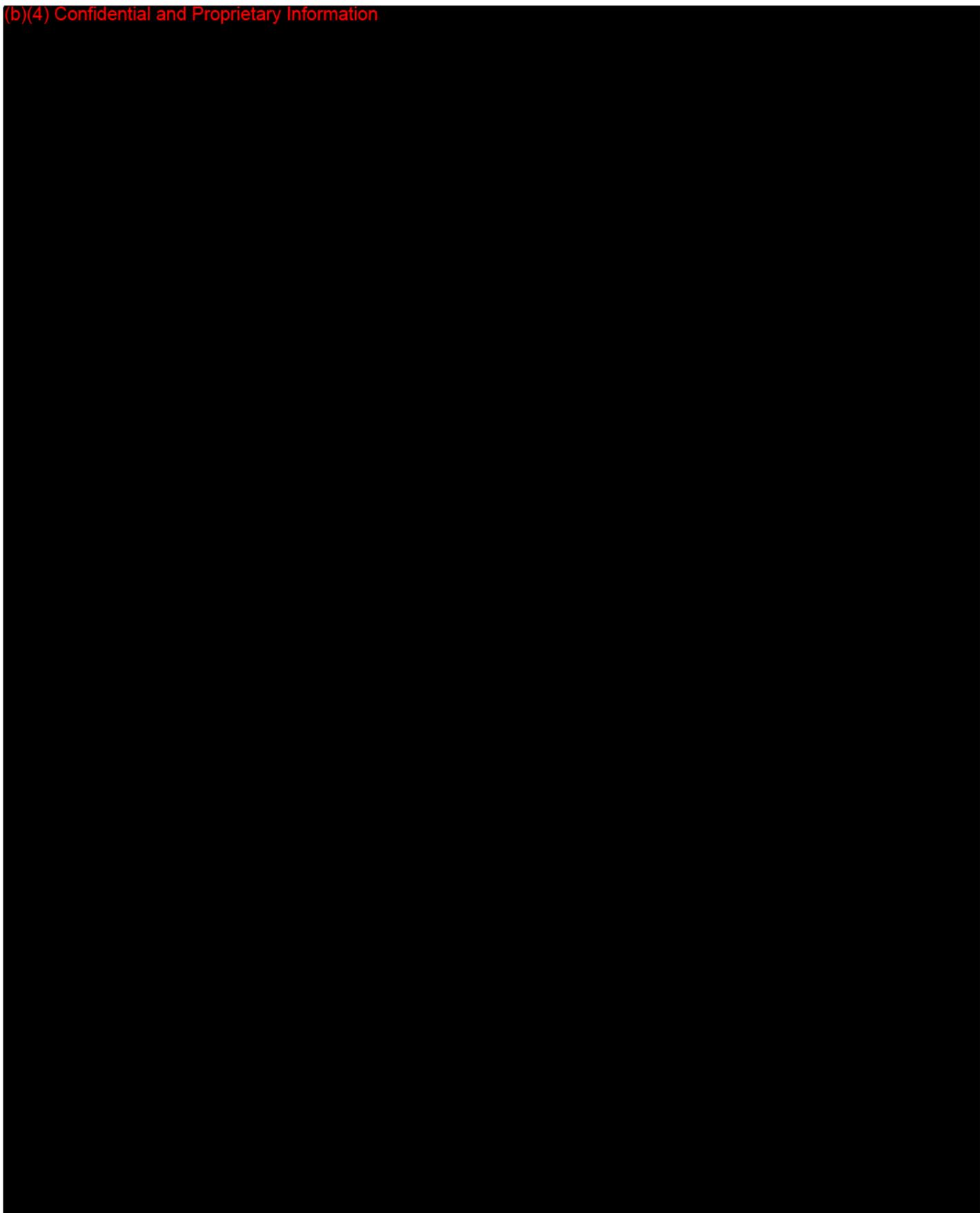
MATERIALS/BIOCOMPATIBILITY

The following table summarizes the patient contacting materials.

(b)(4) Confidential and Proprietary Information

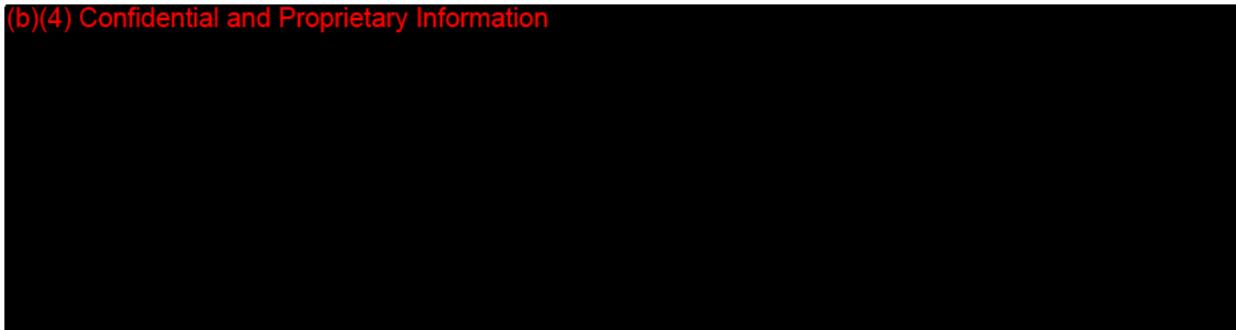
12

(b)(4) Confidential and Proprietary Information



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K062251 – St. Jude Medical, Inc.
Reflexion Spiral Variable Radius Catheter, Model 402804

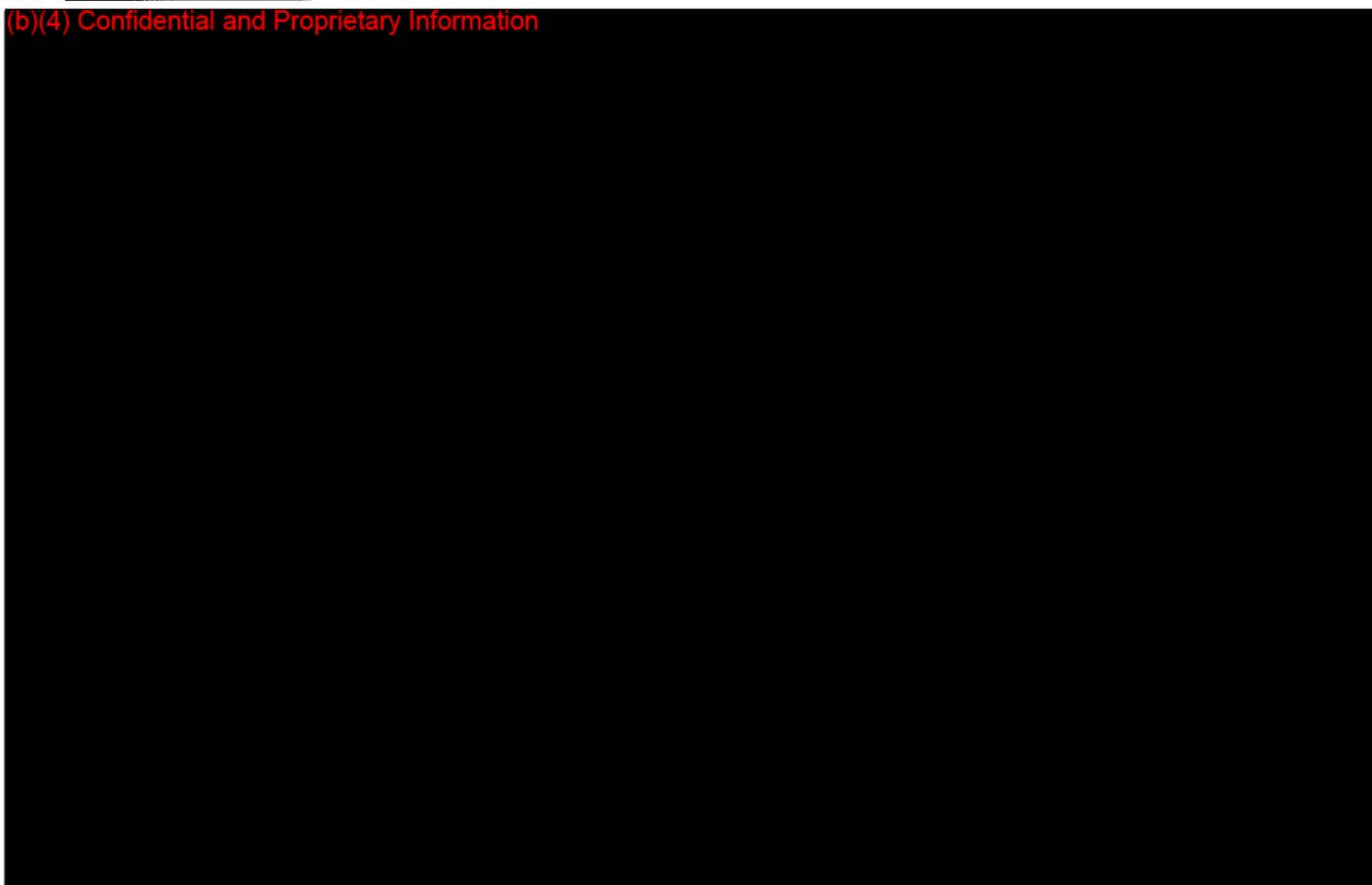
(b)(4) Confidential and Proprietary Information



The results of the biocompatibility testing conducted on the Reflexion Spiral device – cytotoxicity using a MEM elution test and haemocompatibility – are included in appendix G of the submission. All tests passed the acceptance criteria. **The test results raise no biocompatibility concerns.**

STERILIZATION, PACKAGING & SHELF LIFE

(b)(4) Confidential and Proprietary Information

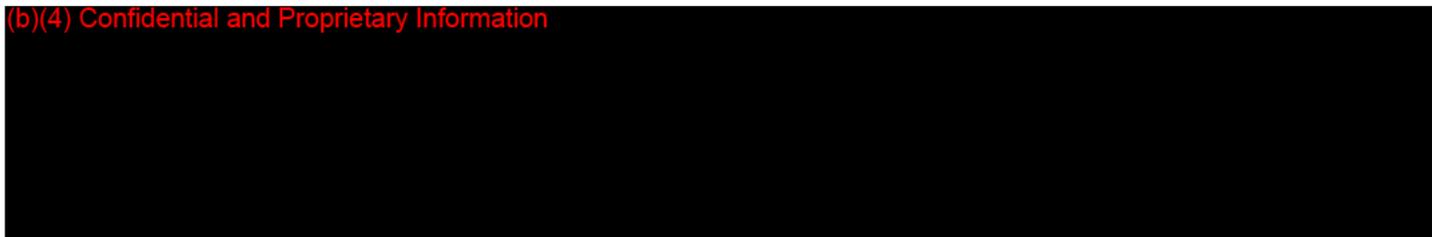


Packaging

(b)(4) Confidential and Proprietary Information

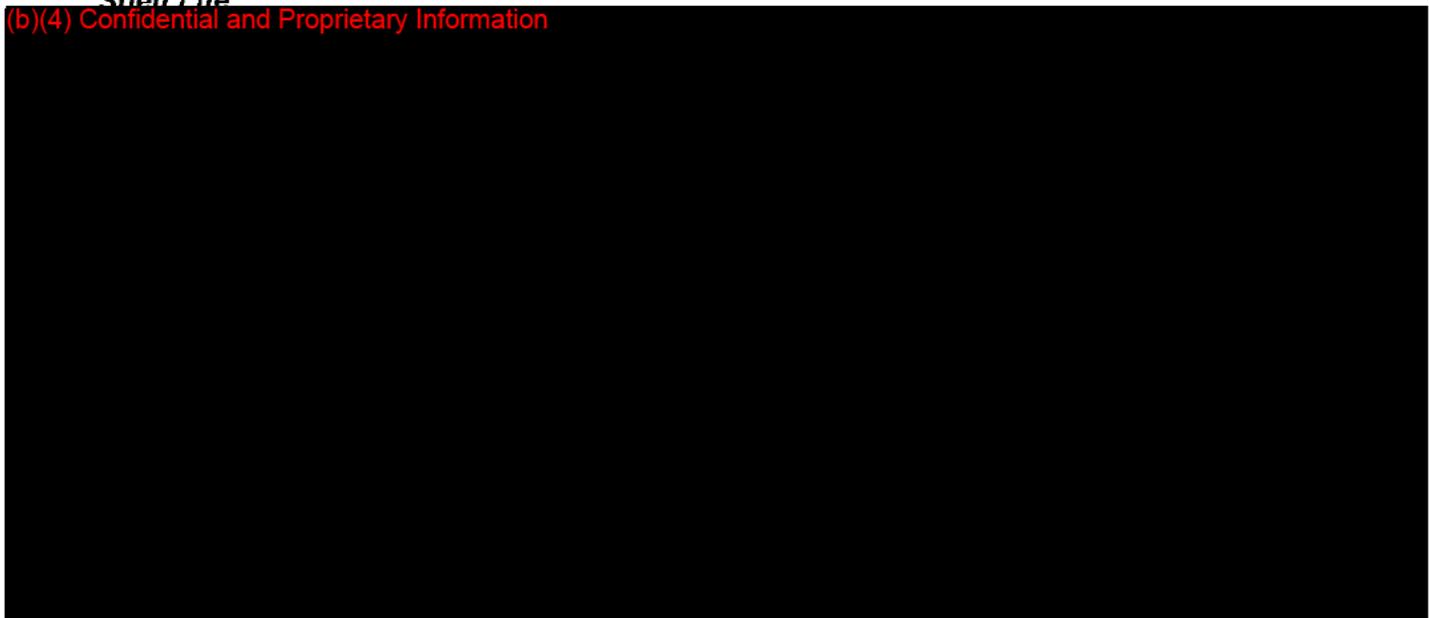


(b)(4) Confidential and Proprietary Information



Shelf Life

(b)(4) Confidential and Proprietary Information

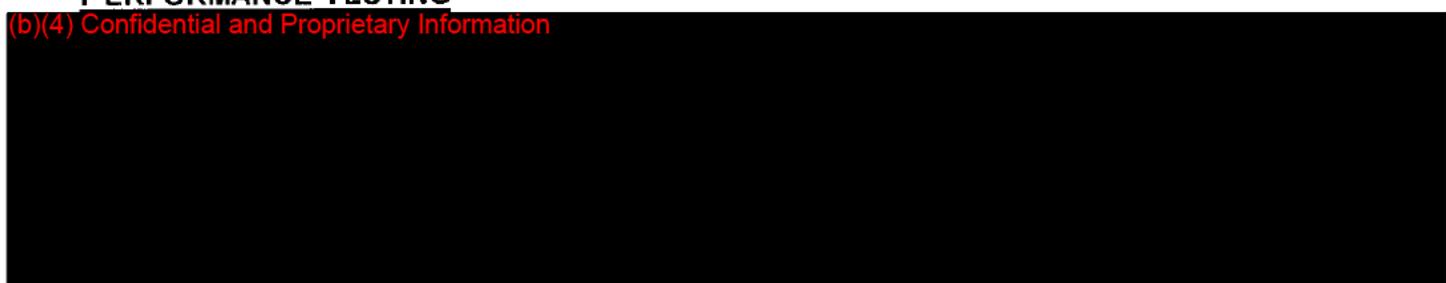


LABELING

The proposed labeling, including the instructions for use and pouch labeling is included in the submission in appendix C. The labeling includes an Rx only symbol, a use by date, a single use symbol, and a 'do not resterilize' symbol. The instructions for use are adequate and do not include any inappropriate claims. **The proposed labeling for the device is therefore adequate.**

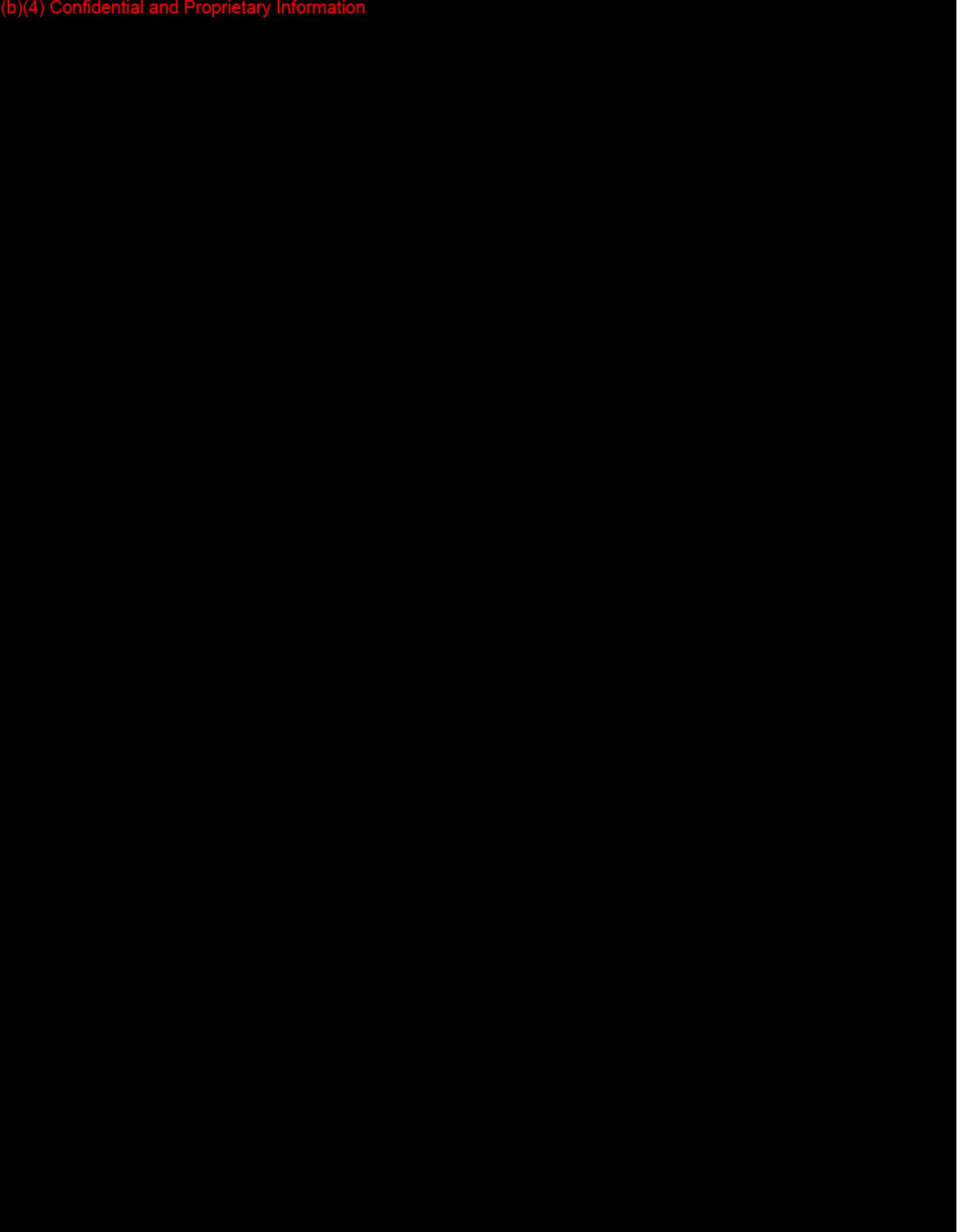
PERFORMANCE TESTING

(b)(4) Confidential and Proprietary Information



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(b)(4) Confidential and Proprietary Information



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K062251 – St. Jude Medical, Inc.
Reflexion Spiral Variable Radius Catheter, Model 402804

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ANIMAL TESTING

(b)(4) Confidential and Proprietary Information



REGULATORY INFORMATION

The sponsor has provided a truth and accuracy statement as required by 21 CFR §807.87, a 510(k) summary in accordance with 21 CFR 807.92, and an indications for use statement.

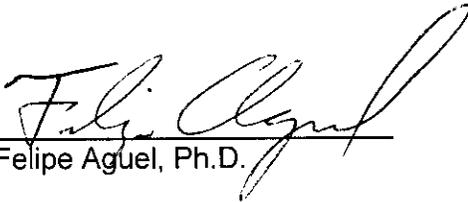
**Page 11 - Review of Traditional 510(k)
K062251 – St. Jude Medical, Inc.
Reflexion Spiral Variable Radius Catheter, Model 402804**

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RECOMMENDATION

I recommend that the proposed device be found **substantially equivalent** to legally marketed mapping catheters, and classified as follows:

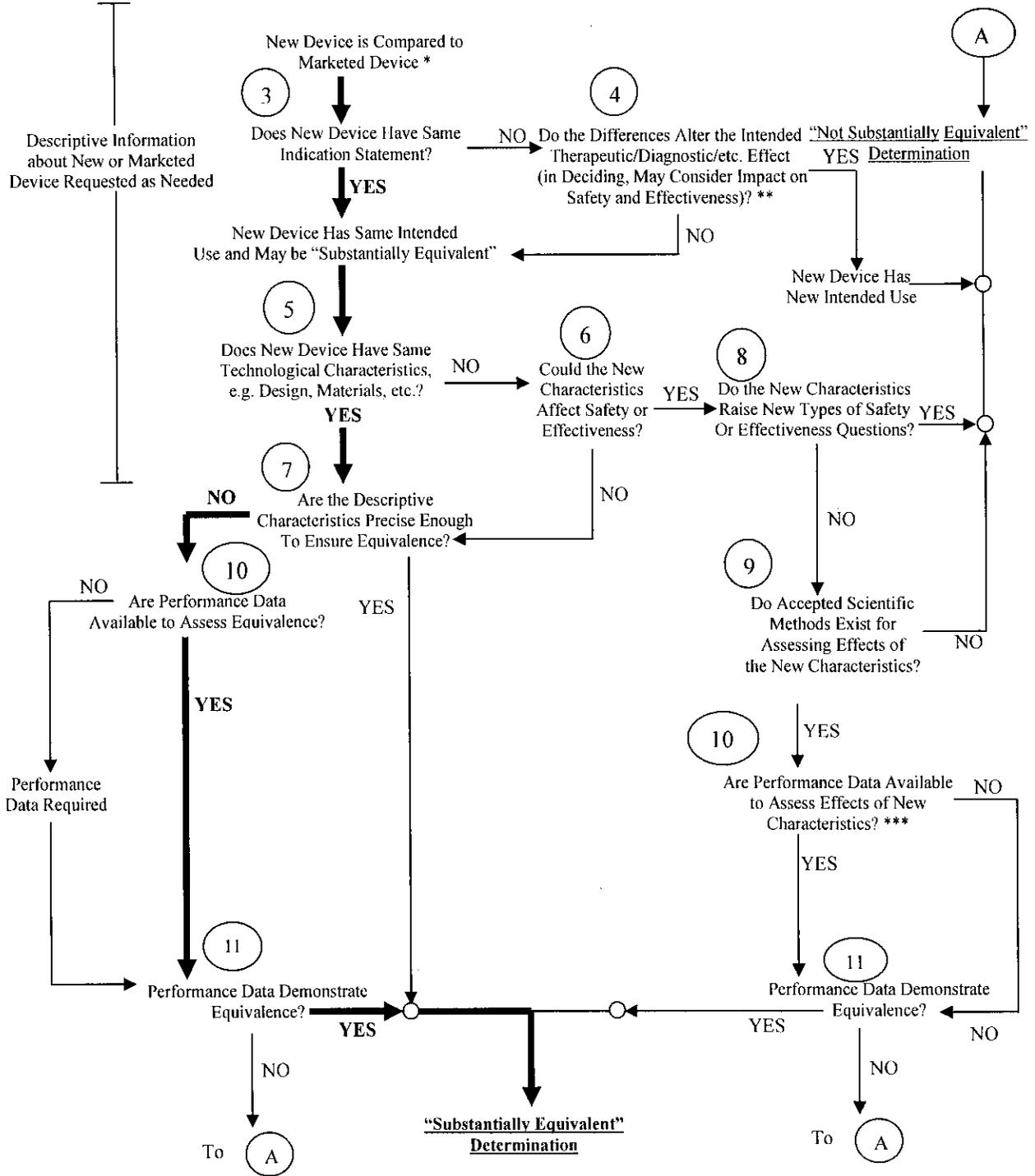
- Class II
- 21 CFR 870.1220
- 74 DRF


Felipe Aguel, Ph.D.

October 16, 2006
Date

 10/16/06

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



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

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