

MAY - 8 2012

Section 5- 510(k) Summary

Submitter : St Jude Medical, CRMD
15900 Valley View Court
Sylmar, CA 91324
Establishment Registration Number: 2017865

Contact Person : Colleen Canan
Staff Regulatory Affairs Specialist
Phone (818) 493 2960
Fax (818) 493 3615

Date Prepared : January 27, 2012

Trade Name : CPS Excel™ MediGuide Enabled™ Guidewire and accessories

Classification : Class II – 21 CFR 870.1330
Catheter, Guidewire

Product Code : DQX

Predicate Device: The subject device is equivalent to the following St Jude Medical and MediGuide Devices

St Jude Medical CPS Courier™ Guidewire (K073082) cleared on January 9, 2008

MediGuide Guided Measurement Catheter (GMC) (K091781) cleared on October 16, 2009

Device Description : The St. Jude Medical CPS Excel™, MediGuide Enabled™ guidewire is a MediGuide enabled guidewire with a hydrophilic coating. The CPS Excel, MediGuide Enabled guidewire contains a magnetic sensor allowing it to be visualized using the MediGuide system

Intended Use: The St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy

Comparison to Predicate Devices The St Jude Medical CPS Excel MediGuide Enabled guidewire has a similar intended use and the same fundamental scientific technology as the

predicate devices. All technological characteristics of CPS Excel MediGuide Enabled guidewire kit are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the subject device and the predicate devices performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the subject device.

Conclusion :

St Jude Medical considers the CPS Excel MediGuide Enabled guidewire kit to be equivalent to the predicate devices listed above. This conclusion is based upon the device similarities in design, technological characteristics, principles of operation, materials and indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MAY - 8 2012

St. Jude Medical
c/o Ms. Colleen Canan
Staff Regulatory Submission Specialist
15900 Valley View Court
Sylmar, CA 91342

Re: K120298
Trade/Device Name: CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Regulatory Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: April 6, 2012
Received: April 10, 2012

Dear Ms. Canan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

Page 2 - Ms. Colleen Canan

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

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

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029

Indications for Use:

The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120298



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUN 13 2012

St. Jude Medical
c/o Ms. Colleen Canan
Staff Regulatory Submission Specialist
15900 Valley View Court
Sylmar, CA 91342

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CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated (Date on orig SE ltr): April 6, 2012
Received (Date on orig SE ltr): April 10, 2012

Dear Ms. Canan:

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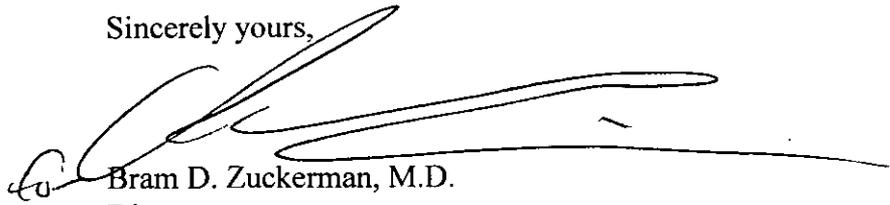
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Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
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AND/OR

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(21 CFR 801 Subpart C)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120298

* * * COMMUNICATION RESULT REPORT (AUG. 13. 2012 2:52PM) * * *

FAX HEADER 1: FDA-CDRH-ODE-POS
FAX HEADER 2:TRANSMITTED/STORED : AUG. 13. 2012 2:51PM
FILE MODE OPTION

ADDRESS

RESULT

PAGE

9291 MEMORY TX

St. Jude Medical

OK

3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWERE-2) BUSY
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

JUN 13 2012

St. Jude Medical
c/o Ms. Colleen Canan
Staff Regulatory Submission Specialist
15900 Valley View Court
Sylmar, CA 91342Re: K120298
CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II (two)
Product Code: 74 DQX
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 6/5

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K120298/01

To: Division Director: CV/DLD

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

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

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

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

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

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

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

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

No response necessary

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

Reviewed by: [Signature]

Date: 6/11/12

all
b/f/y



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

**Premarket Notification [510(k)] Review
Traditional**

K120298/A1

Date: June 11, 2012

To: The Record

From: Frank Lacy

Office: ODE

Division: DCD

510(k) Holder: St. Jude Medical

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire and accessories

Contact: Colleen Canan

Phone: (818) 493-2960

Fax: (818) 493-3615

Email: ccanan@sjm.com

I. Purpose and Submission Summary

The 510(k) holder would like to clarify the Indications for Use for the CPS Excel™ MediGuide Enabled™ Guidewire and accessories.

II. Brief Device Description

The CPS Excel guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The design of the CPS Excel, MediGuide Enabled guidewire is based on the design of the commercially available CPS Courier guidewire (predicate) with the accommodation of a MediGuide sensor. The guidewire contains a magnetic sensor allowing it to be tracked using the MediGuide System.

Like its predicate device, the CPS Excel MediGuide Enabled guidewire is intended for use in the coronary and peripheral vasculature. The diameter of the guidewire is sized to allow it to pass through the lumen of a LV pacing lead. The MediGuide enabled guidewire has three distinct regions: proximal connector region, middle region (guidewire body), and the distal tip region.

The Mediguide™ extension cable accessory is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire via the MediGuide guidewire connector to the Mediguide™ System.

III. Indications for Use

Cleared in initial 510(k):

According to the manufacturer, "The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation

within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

New clarified IFU in this amendment:

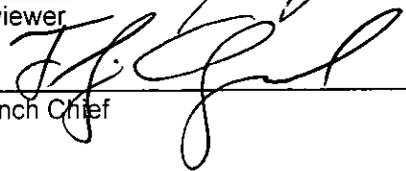
According to the manufacturer, the clarified Indications for Use are, "The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature **(such as to facilitate left heart lead implantation)**. The MediGuide system is intended for use as an adjunct to fluoroscopy.

Note: The additional wording, for clarification is in **BOLD**.

XII. Recommendation

Based on the e-mails (attached), there appears to be no opposition to the clarification which does not alter the cleared Indications for Use. Since this is the case, I recommend that we send a Corrected SE letter indicating our findings.

Reviewer 

Branch Chief 

Date 6/11/12

Date 6/13/2012

Date

Lacy, Frank

From: Shein, Mitchell J.
Sent: Thursday, May 24, 2012 10:39 AM
To: Aguel, Felipe
Cc: Lacy, Frank
Subject: RE: K120298 CPS Excel MediGuide Enabled Guidewire and accessories
Follow Up Flag: Follow up
Flag Status: Orange

In general I don't have an objection as this is the path of least additional work. However, this might change the predicate device if it wasn't indicated for this purpose. But you two are more expert in the ways of 510k's, and I'd gladly defer to your judgement.

Mitchell Shein, Chief

Pacing, Defibrillation and Leads Branch

Division of Cardiovascular Devices

o) 301-796-6363

f) 301-847-8116

mitchell.shein@fda.hhs.gov

From: Aguel, Felipe
Sent: Thursday, May 24, 2012 10:03 AM
To: Shein, Mitchell J.
Cc: Lacy, Frank
Subject: FW: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Mitchell,

Please see the email chain below regarding a change in IFU statement being proposed as an add to file (to include 'such as to facilitate left heart lead implantation'). Do you have any objection?

Felipe

Felipe Aguel, Ph.D.
Branch Chief
FDA/CDRH
Division of Cardiovascular Devices
Cardiac Electrophysiology and Monitoring Branch
Tel: (301) 796-2467
Fax: (301) 847-8116

WO66-1312
10903 New Hampshire Avenue
Silver Spring MD 20993

From: Lacy, Frank
Sent: Thursday, May 24, 2012 10:00 AM
To: Cavanaugh, Kenneth J; Pamidimukkala, Geeta K; Kaushiva, Anchal
Cc: Shulman, Marjorie G.; Aguel, Felipe; Lacy, Frank
Subject: RE: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

I was the lead reviewer and will go with the recommendation that has been made. I have no objections to an add-to-file.

Thanks,
Frank

From: Cavanaugh, Kenneth J
Sent: Thursday, May 24, 2012 9:10 AM
To: Pamidimukkala, Geeta K; Kaushiva, Anchal
Cc: Lacy, Frank; Shulman, Marjorie G.
Subject: RE: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Hi Geeta,

I discussed this with Lisa Lim since ICDB and PVDB were both involved in the review, and we both feel this type of change could be submitted as an add-to-file provided CEMB agrees (since this is their file).

Thanks,

Ken

From: Pamidimukkala, Geeta K
Sent: Wednesday, May 23, 2012 3:52 PM
To: Cavanaugh, Kenneth J; Kaushiva, Anchal
Cc: Lacy, Frank; Shulman, Marjorie G.
Subject: FW: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Hi Ken and Anchal,

I just talked to Frank and he directed me to you both. I was hoping you could weigh in on the proposed change to the IFU below. The sponsor would like to modify the IFU and I wanted to know if their proposed change is acceptable and wouldn't need a new 510k. If you are amenable, we can have them send in an add-to-file to change the IFU. We can then issue a corrected SE and update the database with the new IFU. Otherwise, we'll instruct the sponsor to submit a new 510k for the change.

Guidewire

Current: The guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is

intended for use as an adjunct to fluoroscopy.

New: The guidewire is intended for use with the MediGuide System to enable real-time tip positioning and navigation within the peripheral and coronary vasculature (such as to facilitate left heart lead implantation). The MediGuide system is intended for use as an adjunct to fluoroscopy.

Thanks,
Geeta

From: Shulman, Marjorie G.
Sent: Monday, May 21, 2012 9:48 AM
To: Pamidimukkala, Geeta K
Subject: FW: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Hi Geeta,

Will you please respond to Colleen either via email or phone? I am sending a voicemail next.

Thanks,

Marjie

Marjorie Shulman

Director, Premarket Notification (510(k)) Program
Program Operations Staff
ODE/CDRH/FDA, WO66-1536
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(301) 796-6572
Marjorie.Shulman@FDA.HHS.GOV

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From: Lacy, Frank
Sent: Friday, May 18, 2012 1:41 PM
To: Canan, Colleen
Cc: Shulman, Marjorie G.; Garcia, Diane
Subject: RE: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Hi Ms. Canan,

Please contact Ms. Marjorie Shulman or Diane Garcia of the 510(k) staff for assistance. They can be reached at 301-796-6572 and 301-796-6559, respectively. I have also copied them on this e-mail.

Thanks,
Frank

From: Canan, Colleen [<mailto:CCanan@sjm.com>]

Sent: Friday, May 18, 2012 1:33 PM
To: Lacy, Frank
Subject: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Dear Mr. Lacy-

I have a question about this recently cleared 510(K) and not sure if I should direct this question to you or if you could recommend someone I could direct this question to. St. Jude Medical has been asked by our Notified Body to update the Indication for Use for this product by adding a clarification into the statement. Below is our current Indication for Use Statement followed by the proposed statement that just adds a clarification.

Guidewire

Current: The guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

New: The guidewire is intended for use with the MediGuide System to enable real-time tip positioning and navigation within the peripheral and coronary vasculature (such as to facilitate left heart lead implantation). The MediGuide system is intended for use as an adjunct to fluoroscopy.

Would it be possible for me to send this in as a administrative change and send in an updated Indication for Use statement sheet?

Any assistance you could provide would be much appreciated.

Sincerely

Colleen Canan, RAC
Staff Regulatory Affairs Specialist
St. Jude Medical
818-493-2960

This communication, including any attachments, may contain information that is proprietary, privileged, confidential or legally exempt from disclosure. If you are not a named addressee, you are hereby notified that you are not authorized to read, print, retain a copy of or disseminate any portion of this communication without the consent of the sender and that doing so may be unlawful. If you have received this communication in error, please immediately notify the sender via return e-mail and delete it from your system.

Lacy, Frank

From: Pamidimukkala, Geeta K
Sent: Thursday, June 07, 2012 11:20 AM
To: Lacy, Frank
Cc: Shulman, Marjorie G.; McCabe-Janicki, Margaret; Jones, Edwena
Subject: RE: K120298 CPS Excel MediGuide Enabled Guidewire and accessories
Follow Up Flag: Follow up
Flag Status: Orange

Hi Frank,

Please draft the corrected SE letter and send it to 510k staff. Also, please prepare a brief memo explaining that the change to the IFU is a clarification and does not alter the cleared IFU. I also suggest printing this email chain with Ken's concurrence and adding it to the file/memo.

Best,
Geeta

From: Lacy, Frank
Sent: Thursday, June 07, 2012 9:08 AM
To: Pamidimukkala, Geeta K
Subject: RE: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Hi Geeta,

I am processing it as a CORRECTED SE letter as you suggested earlier.

Thanks,
Frank

From: Lacy, Frank
Sent: Wednesday, June 06, 2012 3:24 PM
To: Pamidimukkala, Geeta K
Subject: FW: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Hi Geeta,

I am assuming the change is alright. How should I process the amendment to the file? It has come in.

Thanks,
Frank

From: Cavanaugh, Kenneth J
Sent: Thursday, May 24, 2012 9:10 AM
To: Pamidimukkala, Geeta K; Kaushiva, Anchal
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Marjie

Marjorie Shulman
Director, Premarket Notification (510(k)) Program
Program Operations Staff

ODE/CDRH/FDA, WO66-1536
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002
 (301) 796-6572

Marjorie.Shulman@FDA.HHS.GOV

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Subject: K120298 CPS Excel MediGuide Enabled Guidewire and accessories

Dear Mr. Lacy-

I have a question about this recently cleared 510(K) and not sure if I should direct this question to you or if you could recommend someone I could direct this question to. St. Jude Medical has been asked by our Notified Body to update the Indication for Use for this product by adding a clarification into the statement. Below is our current Indication for Use Statement followed by the proposed statement that just adds a clarification.

Guidewire

Current: The guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

New: The guidewire is intended for use with the MediGuide System to enable real-time tip positioning and navigation within the peripheral and coronary vasculature (such as to facilitate left heart lead implantation). The MediGuide system is intended for use as an adjunct to fluoroscopy.

Would it be possible for me to send this in as a administrative change and send in an updated Indication for Use statement sheet?

Any assistance you could provide would be much appreciated.

Sincerely

Colleen Cañan, RAC
Staff Regulatory Affairs Specialist
St. Jude Medical
818-493-2960

This communication, including any attachments, may contain information that is proprietary, privileged, confidential or legally exempt from disclosure. If you are not a named addressee, you are hereby notified that you are not authorized to read, print, retain a copy of or disseminate any portion of this communication without the consent of the sender and that doing so may be unlawful. If you have received this communication in error, please immediately notify the sender via return e-mail and delete it from your system.

MAY. 15. 2012 12:09PM

NO. 5310 P. 1/3



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

RECEIVED MAY 15 2012

MAY - 8 2012

St. Jude Medical
c/o Ms. Colleen Canan
Staff Regulatory Submission Specialist
15900 Valley View Court
Sylmar, CA 91342

Re: K120298

Trade/Device Name: CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Regulatory Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: April 6, 2012
Received: April 10, 2012

Dear Ms. Canan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

MAY. 15. 2012 12:09PM

NO. 5310 P. 2/3

Page 2 - Ms. Colleen Canan

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

MAY. 15. 2012 12:09PM

NO. 5310 P. 3/3

RECEIVED MAY 15 2012

K120298

Page 14

Indications for Use

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029

Indications for Use:

The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120298

K120298/A1



St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, CA 91342-3577 USA
Tel 818 362 6822
800 423 5611
www.sjm.com

June 4, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

JUN - 5 2012

Received 104

RE: Add to File: K120298 CPS Excel MediGuide Enabled Guidewire

Dear Sir/Madam:

St. Jude Medical is submitting an Add to File for K120298 CPS Excel MediGuide Enabled Guidewire to add a minor clarification to the Indication for Use Statement.

The Current Cleared Indication for Use Statement:

The guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide System is intended for use as an adjunct to fluoroscopy.

The New (clarification added) Indication for Use Statement:

The guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the peripheral and coronary vasculature (such as to facilitate left heart lead implantation). The MediGuide System is intended for use as an adjunct to fluoroscopy.

Please feel free to contact me at (818) 493-2960 or via fax at (818) 493-3615 regarding this update to K120298.

Sincerely,

Colleen Canan
St. Jude Medical, CRMD
818-493-2960 (phone – direct)
818-493-3615 (fax)
ccanan@sjm.com (email)

Indications for Use

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029

Indications for Use:

The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature (such as to facilitate left heart lead implantation). The MediGuide system is intended for use as an adjunct to fluoroscopy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MAY - 8 2012

St. Jude Medical
c/o Ms. Colleen Canan
Staff Regulatory Submission Specialist
15900 Valley View Court
Sylmar, CA 91342

Re: K120298
Trade/Device Name: CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Regulatory Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: April 6, 2012
Received: April 10, 2012

Dear Ms. Canan:

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Page 2 - Ms. Colleen Canan

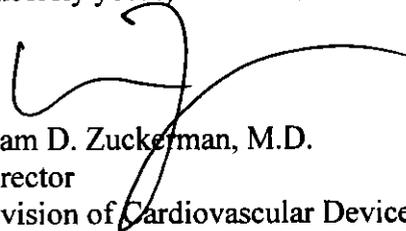
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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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

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029

Indications for Use:

The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120298



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 10, 2012

ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISI
15900 VALLEY VIEW CT.
SYLMAR, CALIFORNIA 91342
ATTN: COLLEEN CANAN

510k Number: K120298

Product: CPS EXCEL MEDIGUIDE ENABLED GU

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Tuesday, April 10, 2012 12:22 PM
To: 'ccanan@sjm.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES**Public Health Service**

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

April 10, 2012

CANAN
COLLEEN

ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISI
 15900 VALLEY VIEW CT.
 SYLMAR, CALIFORNIA 91342
 ATTN: COLLEEN CANAN

510k Number: K120298

Product: CPS EXCEL MEDIGUIDE ENABLED
 GU

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Sincerely,
 510(k) Staff

38



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 29, 2012

ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISI
15900 VALLEY VIEW CT.
SYLMAR, CALIFORNIA 91342
ATTN: COLLEEN CANAN

510k Number: K120298

Product: CPS EXCEL MEDIGUIDE ENABLED GU

On Hold As of 3/26/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModer nizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. 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. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Records processed under FOIA Request # 2015-3395, Released by CDRH on 09-25-2015
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Thursday, March 29, 2012 8:42 AM
To: 'ccanan@sjm.com'
Subject: Hold Letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES**Public Health Service**

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center W066-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-4002

March 29, 2012

CANAN
COLLEEN

ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISI
 15900 VALLEY VIEW CT.
 SYLMAR, CALIFORNIA 91342
 ATTN: COLLEEN CANAN

510k Number: K120298

Product: CPS EXCEL MEDIGUIDE ENABLED GU

On Hold As of 3/26/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 31, 2012

ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISI
15900 VALLEY VIEW CT.
SYLMAR, CALIFORNIA 91342
ATTN: COLLEEN CANAN

510k Number: K120298

Received: 1/31/2012

Product: CPS EXCEL MEDIGUIDE ENABLED GU

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) 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.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 e-Copy 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

CY/DOED

h/20298



St. Jude Medical
 Cardiac Rhythm Management Division
 15900 Valley View Court
 Sylmar, CA 91342-3577 USA
 Tel: 818-362-6822
 800-423-5611
 www.sjm.com

January 27, 2012

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center (WO66-0609)
 10903 New Hampshire Ave.
 Silver Spring, Maryland 20993-0002

FDA/CDRH/DCC
JAN 31 2012
RECEIVED *K36*

Re: Traditional 510(k) Premarket Notification
 St. Jude Medical, CPS Excel™ Mediguide Enabled™ Guidewire

Dear Sir / Madam:

St. Jude Medical, Cardiac Rhythm Management Division (CRMD) is submitting two copies of a traditional 510(k) Premarket Notification to DMC (one paper copy and one electronic copy) to the Document Mail Center. The electronic copy is identical to the paper copy. This application is requesting market clearance of Class II device: CPS Excel Mediguide Enabled Guidewire model numbers DS2M027, DS2M028, and DS2M029 and accessories. The classification of this product is 21 CFR 870.1330 with a product code of DQX. St. Jude Medical, CRMD is the legal manufacturer of the CPS Excel Mediguide Enabled Guidewire.

This submission was prepared in accordance with the CDRH Guidance for Industry and FDA Staff entitled "Format for Traditional and Abbreviated 510(k)s" issued on August 12, 2005.

Questions	YES	NO
Is the device intended for prescription (21CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 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
If yes, does this device type require reprocessed validation data?		
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

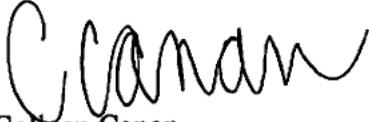
As required by the Federal Food, Drug and Cosmetic Act as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and following the User Fee Rates as published in the Federal Register of October 1, 2009 a copy of the completed Medical Device

User Fee Cover Sheet and a copy of the check follow this letter. The Payment Identification number is (b)(4)

St. Jude Medical CRMD considers this application confidential and claims the protection against public disclosure described in 21 CFR 807.95.

If there are any questions regarding this submission please do not hesitate to contact me at (818) 493-2960 or via fax at (818) 493-3615.

Sincerely,



Colleen Canan
Regulatory Affairs
St. Jude Medical CRMD
818-493-2960(phone)
818-493-3615 (fax)
ccanan@sjm.com (email)

CPS Excel™ MediGuide Enabled™ Guidewire

TRADITIONAL 510(K) SUBMISSION

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Section 1- Medical Device User Fee Cover Sheet

A copy of the Medical Device User fee Cover Sheet is provided on the following page.

Form Approved: OMB No. 0910-511. 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. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ST JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT 15900 VALLEY VIEW COURT P O BOX 9221 SYLMAR CA 91342-9221 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7936	2. CONTACT NAME Colleen Canan 2.1 E-MAIL ADDRESS CCanan@sjm.com 2.2 TELEPHONE NUMBER (include Area code) 1818-493-2960 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 408-5226440	
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/oc/mdufma) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. 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 <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 sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. 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)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		16-Jan-2012

Form FDA 3601 (01/2007)

"Close Window" [Print Cover sheet](#)

(b)(4) FOOD & DRUG ADMINISTRATION		CHECK NO: (b)(4)	DATE: 01/18/2012	
VOUCHER	INVOICE	GROSS AMOUNT	DISCOUNT	NET AMOUNT
(b)(4)	(b)(4)	(b)(4)	0.00	(b)(4)
		(b)(4)	0.00	(b)(4)

DETACH AND RETAIN THIS STATEMENT
 THE ATTACHED CHECK IS IN PAYMENT OF ITEMS DESCRIBED ABOVE
 IF NOT CORRECT, PLEASE NOTIFY US PROMPTLY. NO RECEIPT REQUIRED.

REMITTANCE ADVICE

VERIFY THE AUTHENTICITY OF THIS MULTI-TONE SECURITY DOCUMENT. CHECK BACKGROUND AREA CHANGES COLOR GRADUALLY FROM TOP TO BOTTOM.

ST. JUDE MEDICAL
 One Lillehei Plaza
 St. Paul, Minnesota 55117 U.S.A.
 (651) 756-2000

CHECK NO: 1249814
 Wells Fargo Bank, N.A.
 115 Hospital Drive
 Van Wert, OH 45891
 CHECK DATE 01/18/2012

PAY (b)(4)
 TO THE FOOD & DRUG ADMINISTRATION
 ORDER P O BOX 956733
 OF SAINT LOUIS MO 63195-6733

USD***** (b)(4)



(b)(4)

ST. JUDE MEDICAL
 One Lillehei Plaza
 St. Paul, Minnesota 55117 U.S.A.
 (651) 756-2000

FOOD & DRUG ADMINISTRATION
 P O BOX 956733
 SAINT LOUIS MO 63195-6733

ST. JUDE MEDICAL - CRMD - CHECK REQUEST

DATE January 16, 2012

PERIOD _____

PAYABLE TO: FDA
(Food & Drug Administration)

P.O. # (b)(4)

INVOICE # (b)(4)

MAILING ADDRESS: P.O. Box 956733
St. Louis, MO 63195-6733

INVOICE DATE _____

VENDOR # (b)(4)

FEDERAL TAX ID # (b)(4)

Acct/Sub/Dept/Entity

ACCOUNT NUMBER (b)(4)

TOTAL AMOUNT \$ (b)(4)

Cost Center/Project Number:

PROJECT NUMBER (b)(4)

REASON FOR PAYMENT: FDA Submission fees

Project name: Mediguide

Project code: (b)(4)

Submission type: Traditional 510K

check (b)

SPECIAL INSTRUCTIONS: PLEASE RETURN CHECK TO (b)(6)

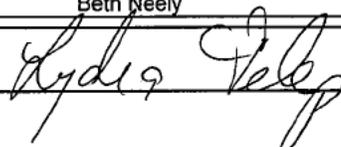
AT EXT. 2127

**PAYMENT
NEEDED BY:** NEXT CHECK RUN

NOTE: Please attach all letters, receipts, invoices, P.O.'s etc. as backup for payment.

Submit completed form, with required signatures and all backup, to the Accounting Department - 938

ORIGINAL SIGNATURES REQUIRED:

Requestor Name (print) <u>(b)(6)</u>	1/16/2012	Approval Name (print) <u>Beth Neely</u>
Requestor Signature <u>(b)(6)</u>	Ext.: 2127	Approval Signature: 

ST. JUDE MEDICAL - CRMD

15900 Valley View Court, Sylmar, CA 91342

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			
Date of Submission 01/27/2012	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)	
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
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	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):
		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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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) 2017865	
Division Name (if applicable) CRM		Phone Number (including area code) (818) 493-2960	
Street Address 15900 Valley View Court		FAX Number (including area code) (818) 493-3615	
City Sylmar	State / Province CA	ZIP/Postal Code 91342	Country USA
Contact Name Colleen Canan			
Contact Title Staff Regulatory Submission Specialist		Contact E-mail Address ccanan@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 <input type="checkbox"/> 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 (<i>specify below</i>)	<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 (<i>specify below</i>)	<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 (<i>specify below</i>)	<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

Other Reason (*specify*):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> 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"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<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		

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
--	---	---

Other Reason (*specify*):

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1 DQX	2 DQO	3	4	
5	6	7	8	

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K073082	CPS Courier Guidewire	St Jude Medical
2	K091780	MediGuide Guided Measurement Catheter	MediGuide
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Part 870.1330 Catheter, Guidewire

	Trade or Proprietary or Model Name for This Device	Model Number
1	CPS Excel MediGuide Enabled guidewire	DS2M027, DS2M028, DS2M029
2		
3		
4		
5		

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

1	2	3	4	5	6
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 DQX	C.F.R. Section (if applicable) 21 CFR 870.1330	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 St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

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 checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name St. Jude Medical		Establishment Registration Number 2017865	
Division Name (if applicable) CRM		Phone Number (including area code) (818) 493-2960	
Street Address 15900 Valley View Court		FAX Number (including area code) (818) 493-3615	
City Sylmar		State / Province CA	ZIP/Postal Code 91342
		Country USA	
Contact Name Colleen Canan		Contact Title Staff Regulatory Submission Specialist	Contact E-mail Address ccanan@sjm.com
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler	
(b)(4)			
Contact Name		Contact Title	Contact E-mail Address
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler	
(b)(4)			
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					
2					
3					
4					
5					
6					
7					

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 3- 510(k) Cover Letter

The SJM 510(k) cover letter is provided on the following page.



St. Jude Medical
 Cardiac Rhythm Management Division
 15900 Valley View Court
 Sylmar, CA 91342-3577 USA
 Tel 818 362 6822
 800 423 5611
 www.sjm.com

January 27, 2012

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center (WO66-0609)
 10903 New Hampshire Ave.
 Silver Spring, Maryland 20993-0002

Re: Traditional 510(k) Premarket Notification
 St. Jude Medical, CPS Excel™ Mediguide Enabled™ Guidewire

Dear Sir / Madam:

St. Jude Medical, Cardiac Rhythm Management Division (CRMD) is submitting two copies of a traditional 510(k) Premarket Notification to DMC (one paper copy and one electronic copy) to the Document Mail Center. The electronic copy is identical to the paper copy. This application is requesting market clearance of Class II device: CPS Excel Mediguide Enabled Guidewire model numbers DS2M027, DS2M028, and DS2M029 and accessories. The classification of this product is 21 CFR 870.1330 with a product code of DQX. St. Jude Medical, CRMD is the legal manufacturer of the CPS Excel Mediguide Enabled Guidewire.

This submission was prepared in accordance with the CDRH Guidance for Industry and FDA Staff entitled "Format for Traditional and Abbreviated 510(k)s" issued on August 12, 2005.

Questions	YES	NO
Is the device intended for prescription (21CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 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
If yes, does this device type require reprocessed validation data?		
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

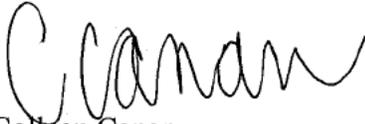
As required by the Federal Food, Drug and Cosmetic Act as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and following the User Fee Rates as published in the Federal Register of October 1, 2009 a copy of the completed Medical Device

User Fee Cover Sheet and a copy of the check follow this letter. The Payment Identification number is (b)(4)

St. Jude Medical CRMD considers this application confidential and claims the protection against public disclosure described in 21 CFR 807.95.

If there are any questions regarding this submission please do not hesitate to contact me at (818) 493-2960 or via fax at (818) 493-3615.

Sincerely,



Colleen Canan
Regulatory Affairs
St. Jude Medical CRMD
818-493-2960(phone)
818-493-3615 (fax)
ccanan@sjm.com (email)

Section 4- Indications for Use statement

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

Indications for Use

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029

Indications for Use:

The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Section 5- 510(k) Summary

Submitter : St Jude Medical, CRMD
15900 Valley View Court
Sylmar, CA 91324
Establishment Registration Number: 2017865

Contact Person : Colleen Canan
Staff Regulatory Affairs Specialist
Phone (818) 493 2960
Fax (818) 493 3615

Date Prepared : January 27, 2012

Trade Name : CPS Excel™ MediGuide Enabled™ Guidewire and accessories

Classification : Class II – 21 CFR 870.1330
Catheter, Guidewire

Product Code : DQX

Predicate Device: The subject device is equivalent to the following St Jude Medical and MediGuide Devices

St Jude Medical CPS Courier™ Guidewire (K073082) cleared on January 9, 2008

MediGuide Guided Measurement Catheter (GMC) (K091781) cleared on October 16, 2009

Device Description : The St. Jude Medical CPS Excel™, MediGuide Enabled™ guidewire is a MediGuide enabled guidewire with a hydrophilic coating. The CPS Excel, MediGuide Enabled guidewire contains a magnetic sensor allowing it to be visualized using the MediGuide system

Intended Use: The St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy

Comparison to Predicate Devices The St Jude Medical CPS Excel MediGuide Enabled guidewire has a similar intended use and the same fundamental scientific technology as the

predicate devices. All technological characteristics of CPS Excel MediGuide Enabled guidewire kit are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the subject device and the predicate devices performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the subject device.

Conclusion : St Jude Medical considers the CPS Excel MediGuide Enabled guidewire kit to be equivalent to the predicate devices listed above. This conclusion is based upon the device similarities in design, technological characteristics, principles of operation, materials and indications for use.

Section 6- Truthful and Accuarte Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

I certify that in my capacity as Staff Regulatory Affairs Specialist of St. Jude Medical, CRM, 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.

CCanan

Signature

Colleen Canan

Typed Name

27-JAN-2012

Date

(Premarket Notification [510(k)] Number)

Section 7- Class III Product Summary and Certification

This is not a class III device and is not substantially equivalent to a class III device; therefore the Literature Search and Certification requirement of the Safe Medical Devices Amendments (SMDA) of 1990 is not applicable.

Section 8 – Financial Certification/ Disclosure Statement

Clinical studies were not required in support of the premarket notification application, thus financial certifications and/or disclosures are not required.

Section 9- Declarations of Conformity and Summary Reports

Declaration of Conformity and Summary Reports are not applicable, as this application is being submitted as a Traditional 510(K).

Section 10- Executive Summary

Concise Description of the Device-CPS Excel MediGuide Enabled Guidewire

The CPS Excel, MediGuide guidewire is a 0.014” MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The guidewire comes in three unique base models distinguished by their unique distal flexibility profiles. Each base model comes with an angled distal tip. The guidewire contains a magnetic sensor allowing it to be tracked using the MediGuide System.

Concise Description of the Accessory- MediGuide Extension Cable

The St Jude Medical MediGuide extension cable is a flexible, insulated cable constructed of metal and plastic materials. This cable is compatible for single use only.

Concise Description of the Accessory- MediGuide Guidewire Connector

The MediGuide guidewire connector is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire to the MediGuide extension cable.

Concise Description of the Accessory- MediGuide Guidewire Torque Clip

The MediGuide torque clip is an accessory that is used to torque the guidewire. It is also used to secure the LV pacing lead and guidewire together. Locking the tip of the CPS Excel MediGuide Enabled guidewire with the tip of a LV pacing lead enables real-time tip visualization and navigation of the LV pacing lead that does not contain a MediGuide sensor.

The CPS Excel, Mediguide Enabled guidewire indication for use is as follows

The St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

The indication for use is substantially equivalent to the referenced predicate device.

Concise Summary for any Performance Testing in the Submission

Performance Testing

Product verification was performed on the CPS Excel MediGuide Enabled guidewire and accessories to confirm they met the design requirements and applicable industry standards. The Functional Verification Report for the CPS Excel MediGuide Enabled guidewire, (b)(4), is provided in **Appendix 1**. The Functional Verification Reports for the accessories: guidewire connector, guidewire torque clip, and extension cable can be found in (b)(4), (b)(4), and (b)(4) respectively (**Appendices 2, 3, and 4**).

Sterilization and Shelf Life

The CPS Excel MediGuide Enabled guidewire, accessory extension cable, and accessory guidewire connector are sterilized using (b)(4). The Sterility Assurance is 10⁻⁶. The sterilization qualification test report for the CPS Excel MediGuide Enabled guidewire is provided in report (b)(4) (Appendix 5).

The accessory extension cable sterilization qualification test report is provided in report (b)(4) (Appendix 6).

The accessory guidewire torque clip sterilization qualification test report is provided in report (b)(4) (Appendix 7).

The accessory guidewire connector qualification test report is provided in report (b)(4) (Appendix 8).

Packaging

The packaging for the CPS Excel MediGuide Enabled guidewire and accessory MediGuide extension cable, guidewire torque clip and guidewire connector are designed to protect the devices from damage and prevent contamination during storage, shipping, handling and introduction to the sterile field. The packaging designs, materials and labeling are compatible with (b)(4) sterilization and capable of providing adequate sterile barrier for the anticipated shelf life of the device.

Shelf Life

SJM is currently requesting a shelf life of 1 year. The testing performed demonstrates the stability and functionality of the CPS Excel MediGuide Enabled guidewire and accessory MediGuide extension cable, guidewire connector and guidewire torque clip. The one year (b)(4) test report simulating one year shelf life storage for the CPS Excel MediGuide Enabled guidewire is provided in (b)(4) (Appendix 9) and the accessory MediGuide extension cable is provided in (b)(4) (Appendix 10). The accessory guidewire connector is provided in (b)(4) (Appendix 11) and the accessory guidewire torque clip is provided in (b)(4) (Appendix 12).

Biocompatibility

According to ANSI/AAMI/ISO 10993-1, "Biological Evaluation of Medical Devices", the fluid path contact components associated with the CPS Excel MediGuide Enabled guidewire is classified as Externally Communicating Device, Circulating Blood with Limited Contact Duration (≤ 24 hours). The MediGuide guidewire torque clip is a product contact device with no direct patient contact. The biocompatibility testing conducted for the guidewire torque clip addresses only the transfer of potential leachables from the guidewire torque clip to the guidewire and ultimately to the patient during use of the guidewire.

The Biocompatibility testing report (b)(4) of the CPS Excel MediGuide Enabled guidewire is attached in Appendix 13 and the Biocompatibility ISO Max testing report (b)(4)

(b)(4) is attached in **Appendix 14**. Biocompatibility testing was also conducted on the accessory guidewire torque clip in (b)(4) (**Appendix 15**).

The accessory MediGuide extension cable and guidewire connector are non patient contacting therefore no biocompatibility testing were required for these accessories.

Substantial Equivalence

St Jude Medical (SJM) has determined that the CPS Excel MediGuide Enabled guidewire is substantially equivalent to the current commercially available SJM and MediGuide devices below

- St Jude Medical CPS Courier guidewire
- MediGuide Measurement Catheter

Comparison information provided in **Table 3** and the supporting performance data (**Appendix 1**) demonstrates the subject device is substantially equivalent to the predicate devices.

Both the CPS Excel MediGuide Enabled guidewire and the predicate CPS Courier guidewire facilitate navigation within the coronary and peripheral vasculature.

The only technology utilized from the MediGuide Measurement Catheter (GMC) is the passive gMPS sensor set which is incorporated internally within the tip of the MediGuide Enabled guidewire to be located or read by the MediGuide gMPS System II (gMPS II) (K102905).

Section 11- Device Description

Intended Use – CPS Excel MediGuide Enabled guidewire:

The St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy

The Intended Use for the accessory extension cable, guidewire connector and guidewire torque clip are:

MediGuide Extension Cable:

The Mediguide extension cable is indicated for use with St Jude Medical MediGuide Enabled products.

MediGuide Guidewire Connector:

The MediGuide guidewire connector is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire to the MediGuide extension cable.

MediGuide Guidewire Torque Clip:

The MediGuide torque clip is an accessory that is used to torque the guidewire. It is also used to secure the LV pacing lead and guidewire together. Locking the tip of the CPS Excel MediGuide Enabled guidewire with the tip of a LV pacing lead enables real-time tip visualization and navigation of the LV pacing lead that does not contain a MediGuide sensor.

Models

The CPS Excel MediGuide Enabled guidewire (drawing (b)(4) **Appendix 16**) consists of guidewires available in different stiffness profiles. The CPS Excel MediGuide Enabled guidewires come in three unique base models distinguished by their unique distal flexibility profiles. Each base model comes with an angled distal tip. The guidewires all come in 195 cm lengths. The accessory extension cable drawing (b)(4) is provided in **Appendix 17**, the accessory guidewire connector drawing (b)(4) is provided in **Appendix 18** and the accessory guidewire torque clip drawing 60036377 is provided in **Appendix 19**.

Table 1 – MediGuide guidewire model numbers

MediGuide
guidewire Model
Numbers:

Model Number	Description
DS2M027	MediGuide guidewire- Soft (S)
DS2M028	MediGuide guidewire- Medium (M)
DS2M029	MediGuide guidewire- Extra Firm (XF)

MediGuide
guidewire
Accessories
packaged with
guidewire:

- Guidewire torque tool
- J-straightener

MediGuide
guidewire
Accessories
packaged separately

Model Number	Description
DS2M030	MediGuide guidewire torque clip
DS2M031	MediGuide extension cable
DS2M032	MediGuide guidewire connector

Device Description

The CPS Excel guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The design of the CPS Excel, MediGuide Enabled guidewire is based on the design of the commercially available CPS Courier guidewire (predicate) with the accommodation of a MediGuide sensor. The guidewire contains a magnetic sensor allowing it to be tracked using the MediGuide System.

Like its predicate device, the CPS Excel MediGuide Enabled guidewire is intended for use in the coronary and peripheral vasculature. The diameter of the guidewire is sized to allow it to pass through the lumen of a LV pacing lead. The MediGuide enabled guidewire has three distinct regions: proximal connector region, middle region (guidewire body), and the distal tip region.

Proximal Connector Region

Electronic interface/connection of the MediGuide guidewire is accomplished at the proximal end of the guidewire. The proximal end contains two (b)(4) rings which are separated and electrically isolated from one another by polymeric rings, as shown in Figure 1. The (b)(4) rings have a diameter similar to that of the guidewire body thus allowing passage through the lumen of a pacing lead. The (b)(4) rings and polymeric rings are supported by a core wire which is bonded to the guidewire body. The sensor cabling runs alongside the core wire and are connected to the platinum iridium rings.

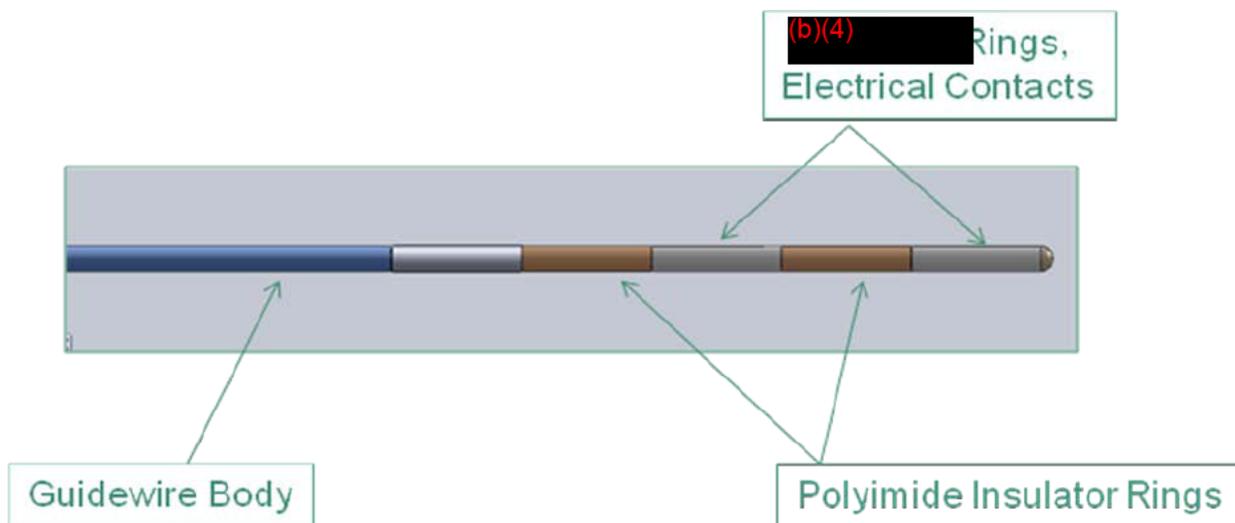


Figure 1: Construction of proximal connector region of CPS Excel MediGuide Enabled guidewire

Middle Region

The guidewire body consists of a hollow (b)(4) tube that provides a lumen for passage of the sensor conductor wires (cables). The (b)(4) tube also contains (b)(4) core wire (safety wire) which is securely attached to both the distal and proximal ends of the

guidewire. The guidewire is coated with (b)(4) to ensure sufficient lubricity to the (b)(4) wire. The predicate CPS Courier guidewire is also coated with (b)(4)

Distal tip region

The distal most component of the Excel guidewire contains the MediGuide Sensor. The sensor is securely attached to the guidewire via the core wire. The MediGuide sensor consists of copper wire coiled around a metal core and connected to a sensor cable. Immediately proximal of the MediGuide sensor is a (b)(4) coil (Pt) which provides radiopacity for tracking on live fluoroscopy. The distal portion of the (b)(4) tube is cut in a helical pattern to provide a flexible tip. The pitch of the cut varies to provide varying degrees of stiffness. The stiffness of the helical cut section increases from proximal to distal, like its predicate wire (CPS Courier). The distal portion of the (b)(4) tube is also ground down to a smaller diameter than the guidewire body. The smaller diameter provides less stiffness and also allows space for a soft polymer (b)(4) coating. The soft polymer coating is identical to the predicate wire and encapsulates the entire distal region of the guidewire including the MediGuide Sensor, as seen in Figure 2. The (b)(4) coating is then coated with a hydrophilic coating to provide lubricity.

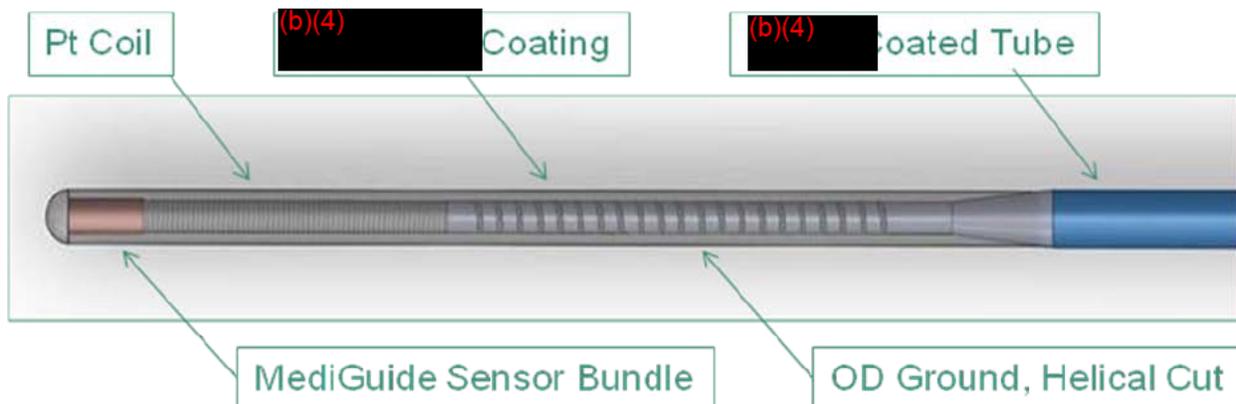


Figure 2: Distal tip region of CPS Excel MediGuide Enabled guidewire

Description of Accessories:

Each guidewire kit contains one guidewire and pouched J-straightener and torque tool. The guidewire is packaged in a spiral dispenser with a luer adapter on the outer end. The dispenser which is retained in its shape with polyethylene clips and has one anti-migration device which grips one point of the wire to prevent its movement within the hoop during transportation. The polymer coated distal tip of the guidewire lies along the outside diameter of the dispenser nearest the luer adapter. Each dispenser assembly and pouched J-straightener and torque tool are placed in an outer pouch and sealed.

The MediGuide™ extension cable accessory is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire via the MediGuide guidewire connector to the MediGuide™ System.

The purpose of the cable is to provide the implanting physician with a sterile connection for the desired delivery tool. The MediGuide Enabled delivery tool needs to be connected to the MediGuide Cath Connect interface box to be able to track the tool on the MediGuide system. The MediGuide extension cable is used to bridge the gap between the MediGuide Cath Connect interface box and the MediGuide Enabled delivery tool. Thus the MediGuide extension cables creates an extra layer of protection by allowing the physician to keep the MediGuide Enabled delivery tool completely in the sterile field and offering the possibility to connect, disconnect and change delivery tools without having to extend beyond the sterile field. The length of the extension cables is sufficient enough to lay them over the sterile drapes without pulling either ends.

The MediGuide extension cable consists of three connectors on each side. The three connectors allow connections of up to three MediGuide Enabled delivery tools to the MediGuide system. The cables that connect to the MediGuide system consists of standard ODU connectors that are plugged into the MediGuide system's Cath Connect box. The other end of the cables is comprised of standard Redel connectors that are magnetically shielded and are compatible with the MediGuide Enabled delivery tools. Trifurcated cables on both ends are color coded respectively to identify correct device connection on both ends, as shown in Figure 3.

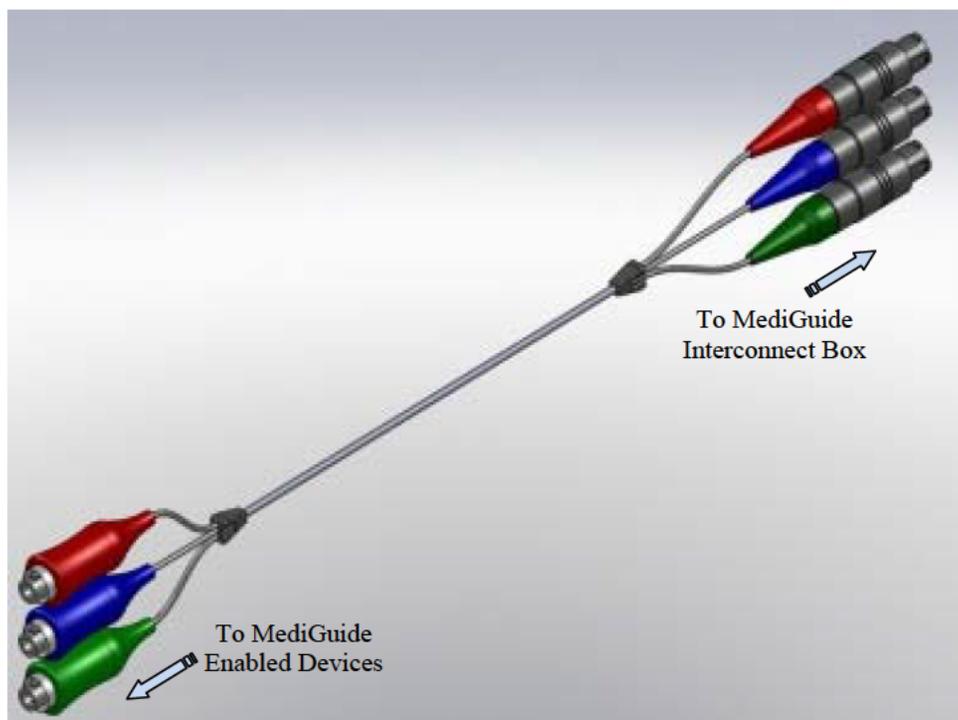


Figure 3: MediGuide Extension Cables

MEDIGUIDE GUIDEWIRE CONNECTOR

The MediGuide guidewire connector accessory (Figure 4) is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire to the MediGuide extension cable. The guidewire is inserted into the connector until it bottoms out. Once the guidewire cannot be pushed any further, the nut on the connector end is tightened to fixate the guidewire in the connector. Inside the molded connector housing is a printed circuit board (PCB) which is wrapped with magnetic shielding. The PCB has contact slots that connect with the electrical contacts of the guidewire for electrical functionality. The other end of the MediGuide guidewire connector is a standard Redel connector that is magnetically shielded and connects to the MediGuide Extension Cable.

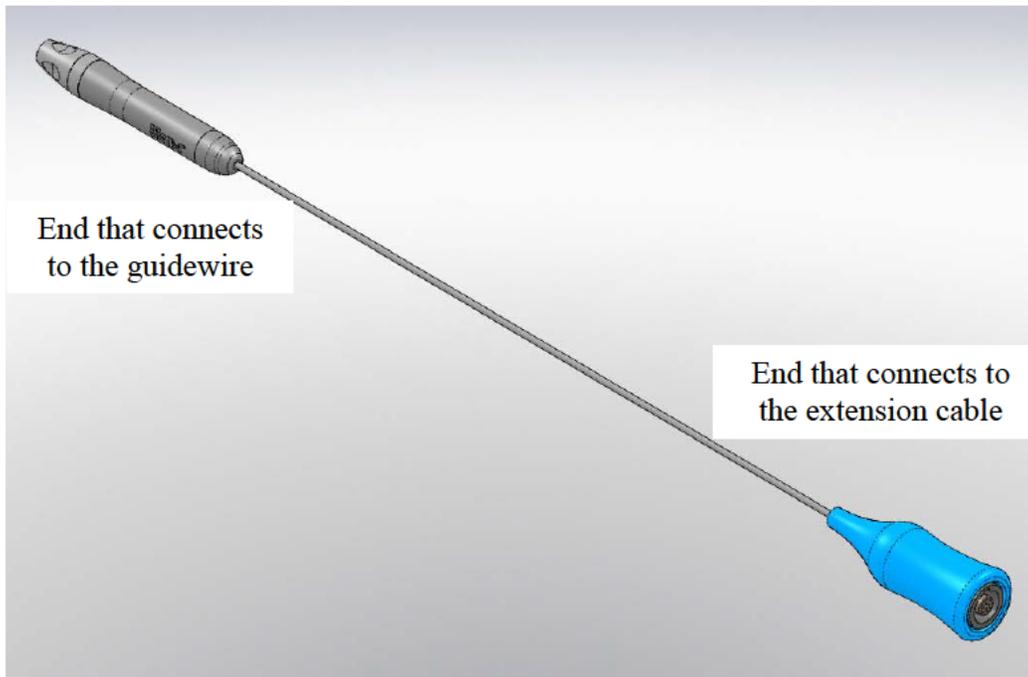


Figure 4: MediGuide Guidewire Connector

MEDIGUIDE GUIDEWIRE TORQUE CLIP

The MediGuide guidewire torque clip is an accessory that is used to torque the guidewire. It is also used to secure the LV pacing lead and guidewire together. Locking the tip of the CPS Excel MediGuide Enabled guidewire with the tip of a LV pacing lead enables real-time tip visualization and navigation of the LV pacing lead that does not contain a MediGuide sensor.

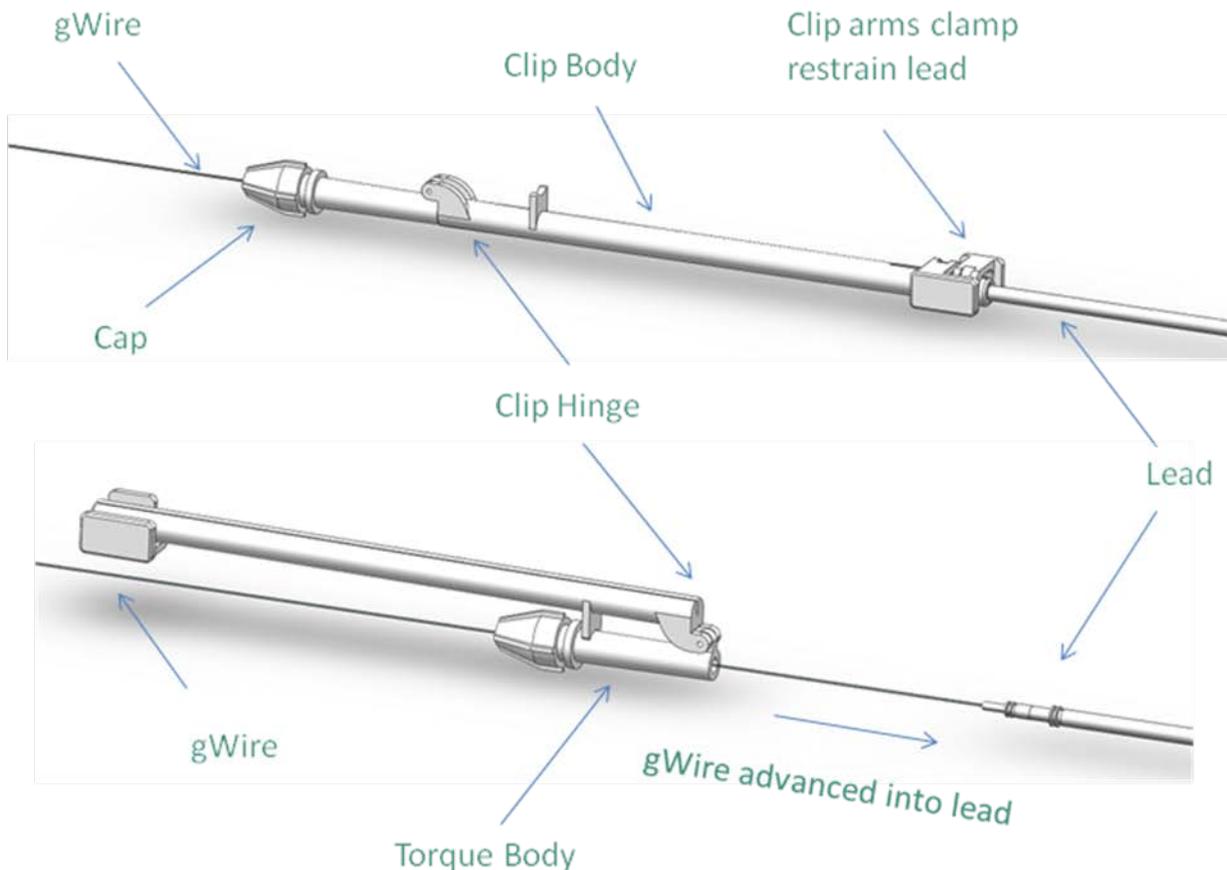


Figure 5: MediGuide Guidewire Torque Clip

The guidewire clip has two (b)(4) (b)(4) molded arms attached by a hinge that allows the clip to pivot over the guidewire path. These arms are defined as the clip body and the torque body, as seen in Figure 5. The end of the clip body that is opposite of the hinge pin includes two opposing clip arms which can be pushed so as to insert or release the lead connector (Figure 5). A graphic of a lead connector is pad printed on one of the clip arms to guide the user in locating the lead connector within the clip arms (Figure 6). The end of the torque body opposite of the hinge pin contains a tightening screen that is used to secure the guidewire to the torque clip.

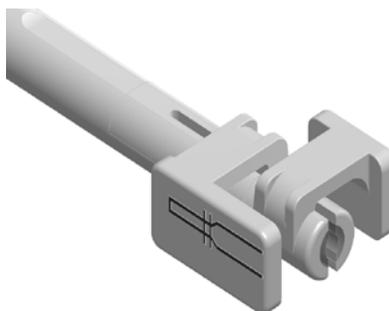


Figure 6: Lead Connector Side of the Torque Clip

The MediGuide Enabled guidewire is passed through the torque clip and the pacing lead as shown in Figure 5. The tip of the guidewire is then matched with the tip of the pacing lead and the nut on the clip is tightened to lock the two together. When inserted inside the anatomy, the implanting physician can now visualize the tip of the pacing lead by using the guidewire sensor locked at its tip. To advance the guidewire past the lead tip, the implanting physician would compress the finger tabs to remove the clip from the lead and advance the clip towards the lead connector. Similar to a typical over-the-wire technique, the physician can now safely track the lead over the wire by holding the guidewire in position and advancing the lead over the wire until it reaches the distal end of the wire. To re-position the guidewire with the tip of the lead, reconnect the clip to the lead connector. Thus the MediGuide guidewire torque clip gives the physician the ability to visualize the lead tip while tracking the lead safely over the wire at the same time. Details on how to use the MediGuide guidewire torque clip can be found in the CPS Excel MediGuide Enabled guidewire Instructions for Use (IFU) manual.

MEDIGUIDE SYSTEM – GUIDED MEDICAL POSITIONING SYSTEM II (K102905)

MediGuide Technology cleared under K102005 on October 29, 2010 is a 3D magnetic tracking system which provides real-time position and orientation of the magnetic sensors embedded in the MediGuide Enabled diagnostic or therapeutic invasive device. These devices are used in vascular or cardiac interventions in the Cath Lab environment. The MediGuide system is integrated with the fluoroscopic imaging system and tracks the sensors continuously within the imaging volume of the fluoroscopic system, on both live fluoroscopy and recorded background. The system is indicated for use as an adjunct to fluoroscopy.

MediGuide system consists of hardware and software elements, which are installed in conjunction with the existing X-ray Imaging System in a Cath Lab. The conventional X-ray Imaging System, equipped with the System elements, continues to perform safely as intended, while enabling device tracking and enhanced visualization tools supplied by MediGuide capabilities. Figure 7 shows the layout of the MediGuide system.

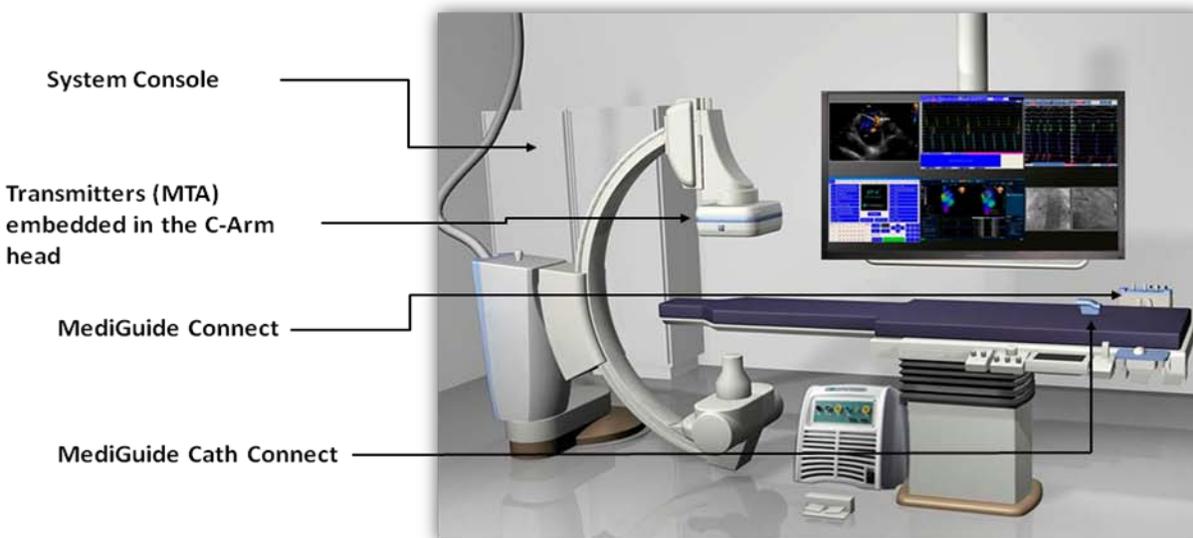


Figure 7: MediGuide System Layout

The hardware element of the system consists of Magnetic Transmitter Assembly (MTA) that generates a controlled magnetic field above the patient's chest. The MTA is assembled on the X-Ray detector. MediGuide Enabled devices that are connected to the system through the MediGuide Cath Connect interface box will be sensed by the system once they enter the magnetic field. For accurate projection of the MediGuide Enabled device, the MediGuide Patient Reference is used to compensate for patient motion along with respiratory compensation. MediGuide Patient Reference is externally attached to the patient chest using the MediGuide Patient Reference Patch. The device projection is also synchronized with the patient's cardiac cycle using the MediGuide ECG recorder.

Figures 8 and 9 show the user interface for the MediGuide screens.

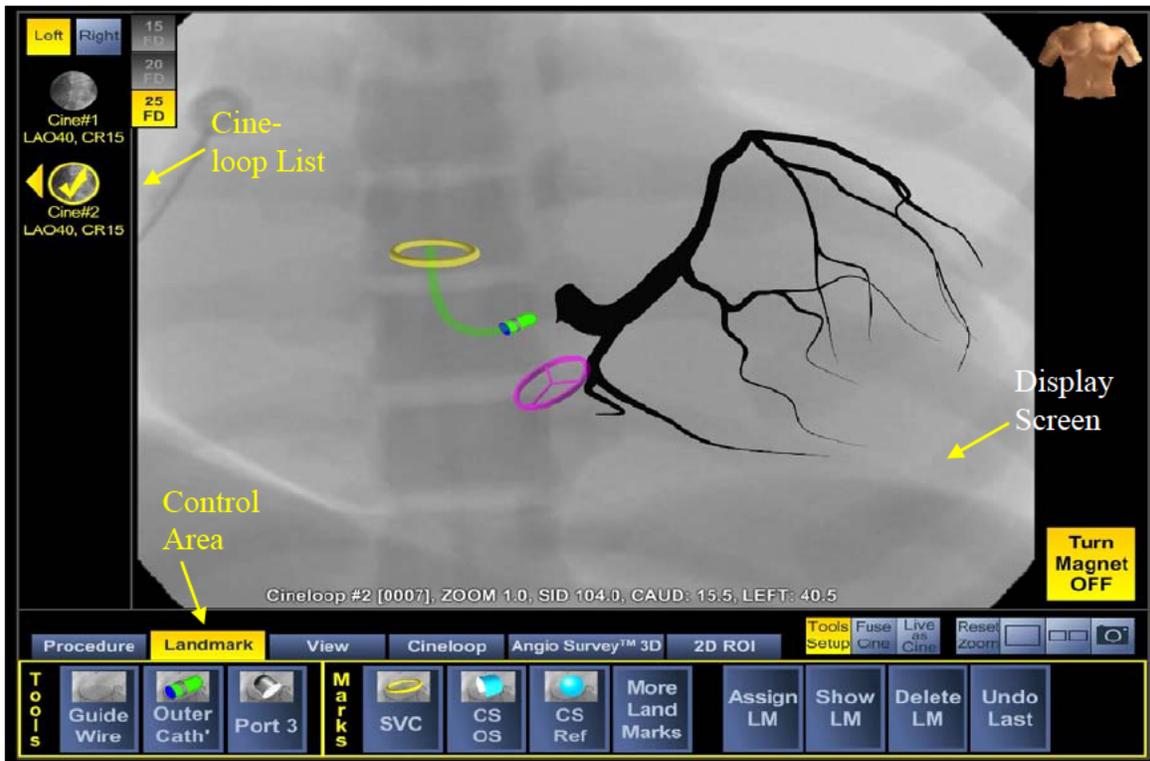


Figure 8: MediGuide Primary Monitor Layout

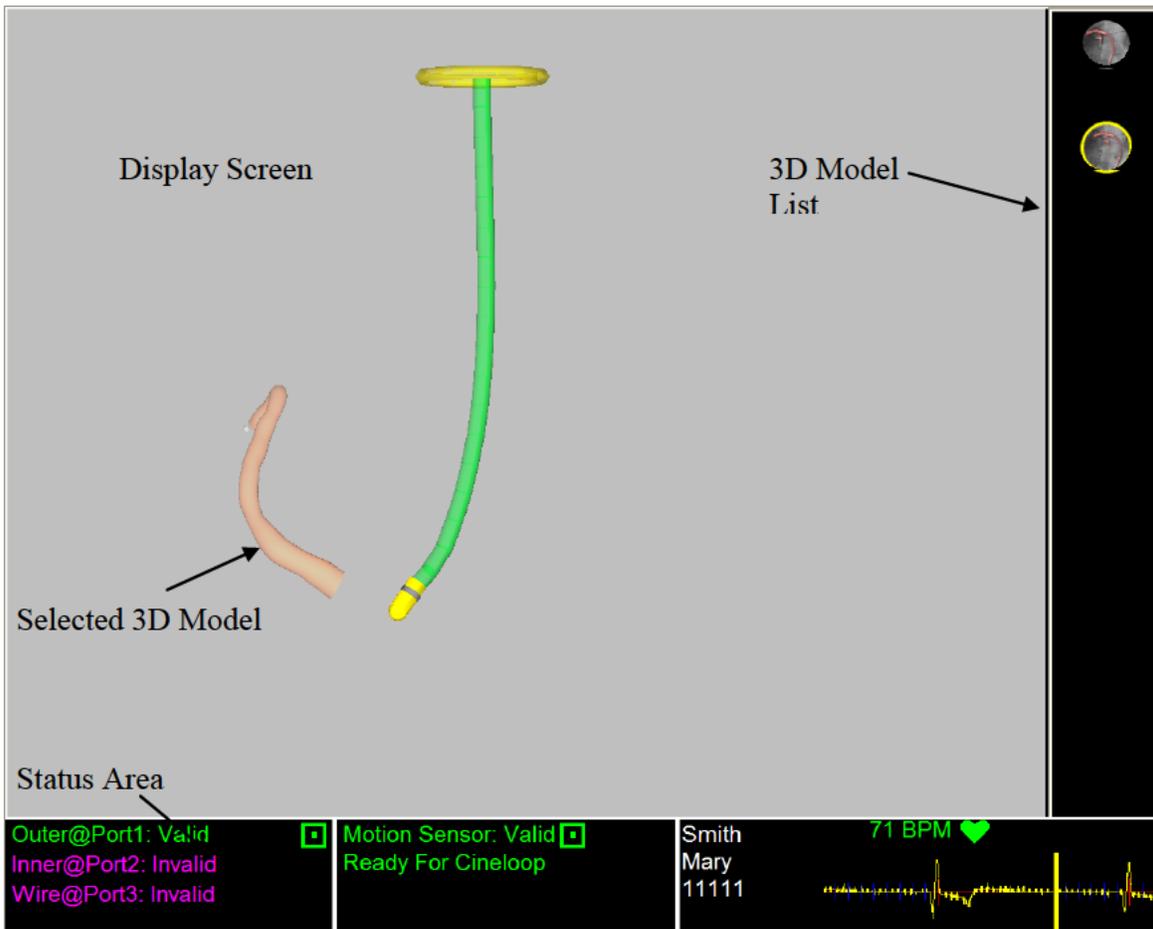


Figure 9: Secondary Monitor Display Layout

The MediGuide system is 510(K) cleared under K102905 October 29, 2010.

Design Requirements and Performance Specifications

Table 2 lists the design requirements and performance specifications for the CPS Excel MediGuide Enabled guidewire and the accessory extension cable, guidewire torque clip and guidewire connector.

Table 2: Design Requirements and Performance Specifications	
Parameter	Requirement/Specification
Dimensional:	<ul style="list-style-type: none"> The guidewire is to be 0.0145” in diameter or less Each guidewire shall be 195 ± 3 cm in length.
Functional Requirement: Guidewire	<ul style="list-style-type: none"> Each guidewire shall have a distal coating consisting of (b)(4) to provide radiopacity. The distal tip coating of the guidewire shall be

	<p>radiopaque.</p> <ul style="list-style-type: none"> • The midsection of each guidewire shall have a (b)(4) coating. The Guidewire (b)(4) coating must withstand 1 insertion and withdrawal into a lead while the lead is placed in labyrinth path. • The distal tip of the guidewire shall incorporate a coil for Radiopacity. The coil shall be (b)(4) • The distal tip will contain a MediGuide sensor. The MediGuide sensor will be contained within the (b)(4) coating and will be attached to the guidewire via the core wire. • The polymer coating will be over-coated with a hydrophilic coating. Each guidewire shall not exhibit any polymer coating damage when inserted into a device 10 times within a vessel model. • Metallic components of the guidewire shall show no signs of corrosion that affects functional performance or biocompatibility test results when tested per the corrosion resistance test method described in annex B of ISO 11070.
Structural Requirements	
Structural Requirements Guidewire	<ul style="list-style-type: none"> • The core wire acts as the safety wire for the device thus the core wire and the distal bond joint must withstand 0.5 lbs of axial load. • The guidewire shall withstand a minimum of 5 turns without failure while a 0.03 lbf tensile force is applied. • The guidewire must track thru a lead when it is placed into a vessel model. • The guidewire must pass the (b)(4) Test described in ISO (b)(4). • The guidewire must pass the (b)(4) Test described in ISO (b)(4).
Electrical Requirements	
Electrical Requirements Guidewire	<ul style="list-style-type: none"> • The proximal section of each guidewire will have electrical connections that provide compatibility with the Guidewire Connector handle/interface cable. The proximal portion

	<p>of the guide wire must withstand five (5) insertion withdrawals into the Guidewire Connector Handle without physical damage or loss of electrical integrity.</p> <ul style="list-style-type: none"> • Electrical Integrity: The electrical resistance across the two conductor rings should be between 200 and 300 ohms. The resistance from each of the conductor rings to the exposed metal on the guidewire body must be greater than 3 mega-ohm. • The electrical integrity must be maintained when the guidewire is inserted into a device 10 times within a vessel model. • The guidewire must maintain its electrical integrity when soaked in 37° C (\pm 2°C) saline for a minimum of 2 hours. • The polarity of the sensor shall be consistently wired to the connector. The sensor coil supply (inner) wire shall be wired to proximal connector ring and the sensor coil return (outer) wire shall be wired to distal connector ring.
Sensor Accuracy Requirements Guidewire	<ul style="list-style-type: none"> • When tested under non-unidirectional AC magnetic field of 10uT, generated from 9 concurrent coils at 10-14kHz, emitted from the MediGuide system MTA (magnetic transmitter assembly) magnetic field vector with the guidewire connector placed 30 cm radially from the edge of the MTA the following is required: <ul style="list-style-type: none"> • Average static positional accuracy error shall be less than 0.5mm with a maximum standard deviation of 0.3mm.
Torque Tool Requirement	<ul style="list-style-type: none"> • The torque tool shall be able to interface with a .014" guidewire to provide 0.2 in-oz of torque to the guidewire.
J-Straightener Requirement	<ul style="list-style-type: none"> • The J-straightener shall act as a funnel making it easier to insert the guidewire into a lead or another compatible device.
MediGuide Guidewire Torque Clip Requirements	<ul style="list-style-type: none"> • The guidewire clip shall be compatible with the MediGuide Enabled Guidewire. The clip shall allow the passage of guidewire without any damage. • The guidewire clip shall be compatible with the 1258 QuickFlex Micro lead and the 1458

	<p>Quartet lead (the lead connector shall fit within the distal overmold portion of the clip).</p> <ul style="list-style-type: none">• When unclipped, the MediGuide Enabled Guidewire is able to be advanced by a minimum of 6.0 cm distally into the lead without the need to detach the clip from the guidewire.• The over mold portion of the clip must not delaminate after applying a minimum of 0.2 lbs axial force 5 times.• The guidewire clip must attach to the 1258 QuickFlex Micro and the 1458 Quartet Lead proximal connector with a minimum of 0.2 lbs axial force 5 times and shall not damage the proximal lead connectors.• The clip (guidewire attachment portion) must be capable of applying 0.2 in-oz torque to the guidewire when it is fixed in place.• The actuation portion of the clip must withstand 5 actuation cycles without damage.• A thumb pad will have a lead connector outline printed upon it in black ink indicating lead connector to clip orientation.• The hinges shall be free of splitting.• The torquer nut shall be restrained by the torquer body.• The hinge portion of the clip must withstand 5 cycles of full range rotation without damage.
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CPS Excel MediGuide Enabled guidewire Packaging

The packaging for the CPS Excel MediGuide Enabled guidewire is designed to protect the device from damage and prevent contamination during storage, shipping, handling and introduction to the sterile field. The packaging design, materials and labeling are compatible with (b) (4) sterilization and capable of providing adequate sterile barrier for the anticipated shelf life of the device.

Each guidewire kit contains one guidewire and pouched J-straightener and torque tool. The guidewire is packaged in a spiral dispenser with a luer adapter on the outer end. The dispenser which is retained in its shape with polyethylene clips and has one anti-migration device which grips one point of the wire to prevent its movement within the hoop during transportation. The polymer coated distal tip of the guidewire lies along the outside diameter of the dispenser nearest the luer adapter. Each dispenser assembly and pouched J-straightener and torque tool are placed in an outer pouch and sealed.

Extension Cable Packaging:

The MediGuide extension cable contains one trifurcated extension cable packaged in a thermoformed tray. The trays are sealed with a (b) (4) lid and packaged in a pouch and box configuration to protect the contents during shipping.

MediGuide Guidewire Torque Clip Packaging:

The MediGuide guidewire torque clip contains one guidewire torque clip packaged in a double pouch configuration. The outer pouch shall provide a sterile barrier.

Mediguide Guidewire Connector Packaging:

The guidewire connector shall be packaged separately in a thermoformed tray. The tray is sealed with a (b) (4) lid and packaged in a pouch and box configuration to protect the contents during shipping.

Section 12- Substantial Equivalence

St Jude Medical (SJM) has determined that the CPS Excel MediGuide Enabled guidewire to be substantially equivalent to the current commercially available SJM and Mediguide devices below:

- St Jude Medical CPS Courier Guidewire (K073082)
- MediGuide Measurement Catheter (GMC) (K091781)

The following discussion and comparative Table 3 provide pertinent comparison information to demonstrate substantial equivalence.

Table 3: Comparison Table

	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009)	MediGuide Measurement Catheter (GMC) (Predicate Device)
		K073082	K091780
Product Code	DQY	DQX	DQO
Regulation	870.1330	870.1330	870.1200
Indications for Use	The St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.	The CPS Courier Guidewires are intended for use in coronary and peripheral vasculature.	The GMC device is a gMPS enabled intravascular catheter intended for the diagnostic evaluation of the coronary vasculature in patients who are candidates for coronary angiography and/or Percutaneous Coronary Intervention (PCI) The GMC is used with compatible

	<p>St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)</p>	<p>St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009)</p>	<p>MediGuide Measurement Catheter (GMC) (Predicate Device)</p>
		<p>K073082</p>	<p>K091780</p> <p>gMPS system to enable real-time tip positioning and navigation, quantitative reconstruction, qualitative 3D foreshortening indications, and landmarking The System is indicated for use as an adjunct to fluoroscopy.</p>
<p>Device Description</p>	<p>The CPS Excel MediGuide Enabled guidewire is a 0.014” MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The key design features are:</p> <ul style="list-style-type: none"> • (b)(4) hypo tube • (b)(4) coated SS • (b)(4) (b)(4) jacketed tip • Hydrophilically coated tip • Copper sensor cable • Copper sensor • Proximal (b)(4) 	<p>The St Jude Medical CPS Courier Guidewire is a 0.014” (b)(4) coated (b)(4) (b)(4) core wire, the distal end of which is reduced in diameter. The key design features are:</p> <ul style="list-style-type: none"> • (b)(4) core wire • (b)(4) coated SS • (b)(4) jacketed tip • Hydrophilically coated tip 	<p>3.5F catheter with a maximal shaft Inner diameter of 1.15 mm, a tapered tip Inner diameter of 0.58 mm, and a usable length of 135 cm</p>

	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009)	MediGuide Measurement Catheter (GMC) (Predicate Device)
	(b)(4) conductor rings • Polyimide spacers	K073082	K091780
OD	0.014"	Same as subject device	3.5 F
Working Length	195 cm	Same as subject device	135 cm
No. of models	3	10	1
Coating	Hydrophilic and (b)(4)	Same as subject device	(b)(4)
Distal End Stiffness	Soft, Medium, & Extra Firm	Extra Soft, Soft, Medium, Firm & Extra Firm	NA
Tip Shape	J-tip	Straight and J-tip	NA
Compatibility with Navigation System	Yes	NA	Same as subject device
Measures Enabled via the Computerized System while working in conjunction with device	Real-time tip positioning and navigation	NA	Same as subject device

	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009)	MediGuide Measurement Catheter (GMC) (Predicate Device)
		K073082	K091780
Sterility	Supplied Sterile	Same as subject device	Same as subject device
Tissue Contacting materials- Ground Hypo Tube	Top Coat: (b)(4) (b)(4)	Same as subject device	NA
Tissue Contacting Materials- Coating	Hydrophilic coating (b)(4)	Same as subject device	NA
Tissue Contacting Materials- Polymer jacket	(b)(4)	Same as subject device	NA

GUIDEWIRE COMPARISONS

The design, technology, operating principles, materials and packaging of the guidewire subject device are very similar as those of the CPS Courier predicate device. The subject device has been modified by adding an encapsulated, passive gMPS sensor set (sensor and cable) within the guidewire. The sensor is located near the distal tip of the guidewire. The sensor and attached cable are positioned along the guidewire interior similar to the predicate GMC catheter.

The subject device incorporates the following modifications to the predicate device:

Table 4

Design Feature	CPS Excel, MediGuide Enabled	CPS Courier	Reason for change
Guidewire body	Hypo tube	Solid core wire	Hypo tube (lumen) needed to route the sensor cable
Proximal end	(b)(4) conductor rings	No conductor rings	Conductor rings are required to connect to the sensor cable and then make a connection to the navigation system
Sensor	Encapsulated sensor at the distal end	No sensor	Sensor required to allow for tracking with a navigation system.

All technological characteristics of CPS Excel MediGuide Enabled guidewire are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the proposed device and the predicate devices performance, testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device.

Section 13- Proposed Labeling

A copy of the Instructions for Use Manuals for the CPS Excel MediGuide Enabled guidewire and the Accessory MediGuide extension cable are provided in **Appendix 20 and Appendix 21**.

Appendix 22 and 23 contains draft labels for the CPS Excel MediGuide Enabled guidewire and the Accessory MediGuide extension cable. **Appendix 24 and 25** contains the draft package labels for the MediGuide torque clip and guidewire connector.

Section 14- Sterilization & Shelf Life

Sterilization

(b)(4) Third Party Information will be the contract sterilizer for the CPS Excel MediGuide Enabled guidewire. The subject device is sterilized using (b)(4) (b)(4) The Sterility Assurance Level is 10⁻⁶.

(b)(4) Third Party Information will be the contract sterilizer for the accessory MediGuide extension cable, MediGuide torque clip, and MediGuide guidewire connector. The subject accessories are sterilized using (b)(4) The Sterility Assurance Level is 10⁻⁶.

An (b)(4) sterilization product qualification was performed to qualify the CPS Excel MediGuide Enabled guidewire and accessory extension cable, torque clip, and guidewire connector by performing (b)(4) (b)(4) (b)(4), (b)(4) (b)(4) testing. The sterilization qualification report for adoption of the CPS Excel MediGuide Enabled guidewire into Cycle (b) is provided in report (b)(4) 1 (Appendix 5). The sterilization qualification reports for adoption of the accessory MediGuide extension cable, torque clip, and guidewire connector into Cycle (b)(4)(b)(4) are provided in sterilization reports (b)(4) (Appendix 6), (b)(4) (Appendix 7), and (b)(4) (Appendix 8), respectively.

Shelf Life- CPS Excel MediGuide Enabled guidewire

SJM is currently requesting a shelf life of 1 year. The testing performed demonstrates the stability and functionality of the CPS Excel MediGuide Enabled guidewire and the separately packaged accessory MediGuide extension cable, torque clip and guidewire connector

The (b)(4) test report simulating (b)(4) for the CPS Excel MediGuide guidewire is provided in (b)(4) (Appendix 9) The (b)(4) test report simulating (b)(4) MediGuide extension cable is provided in (b)(4) (Appendix 10)

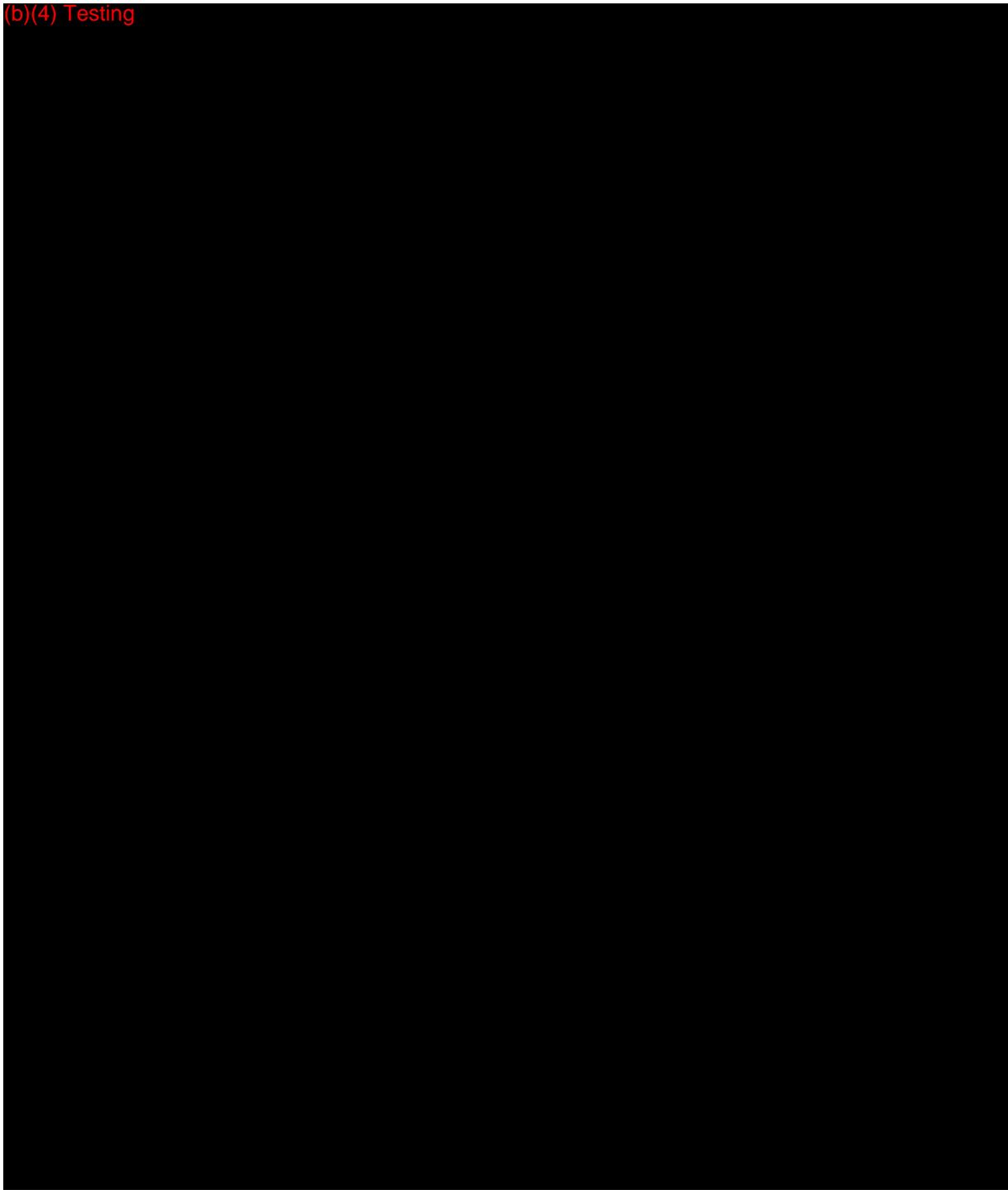
A summary of test results is provided below

Summary of Tests and Results

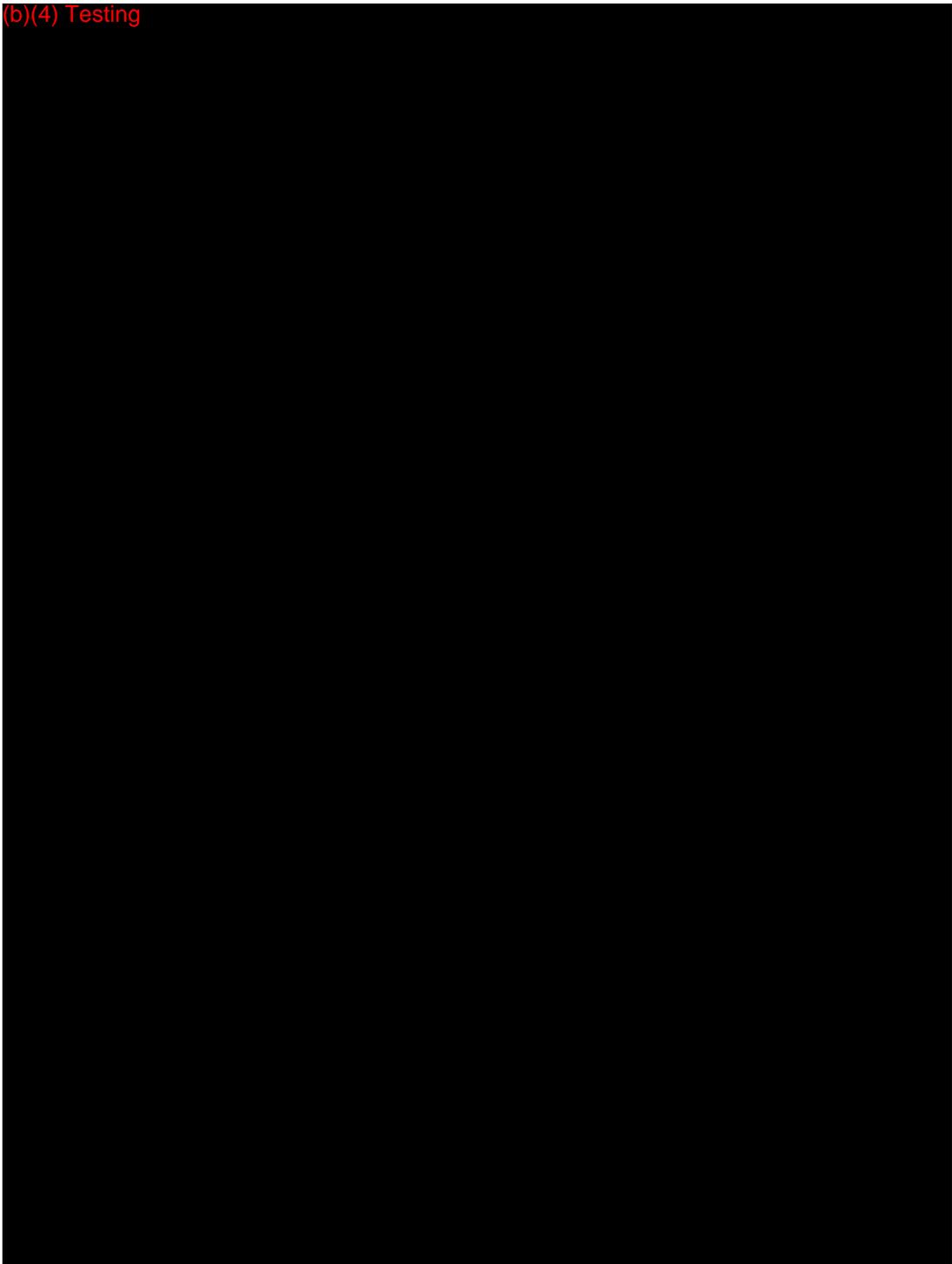
Table 5 (b)(4) **Testing Summary**

Test	Acceptance Criteria	Results
(b)(4)		

(b)(4) Testing



(b)(4) Testing



(b)(4) Testing



Section 15- Biocompatibility

According to ANSI/AAMI/ISO 10993-1, “Biological Evaluation of Medical Devices”, the tissue contact components associated with the CPS Excel Mediguide Enabled guidewire is classified as Externally Communicating Device, Tissue contact with Contact Duration (\leq 24 hours). The MediGuide guidewire torque clip is a product contact device with no direct patient contact. The biocompatibility testing conducted for the guidewire torque clip addresses only the transfer of potential leachables from the guidewire torque clip to the guidewire and ultimately to the patient during use of the guidewire. Device materials that have no potential of coming in contact with tissue are not listed.

The accessory MediGuide extension cable (DS2M031) and guidewire connector (DS2M032) are non patient contacting and therefore no biocompatibility testing is required.

The table below identifies the device components and tissue contacting materials for the CPS Excel MediGuide Enabled guidewire and torque clip.

Table 6

St. Jude Medical CPS Excel MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029	
Part name	Raw material
Ground Hypo Tube	Top Coat: (b)(4) (b)(4)
Coating	Hydrophilic Coating (b)(4)
Polymer Jacket	(b)(4)

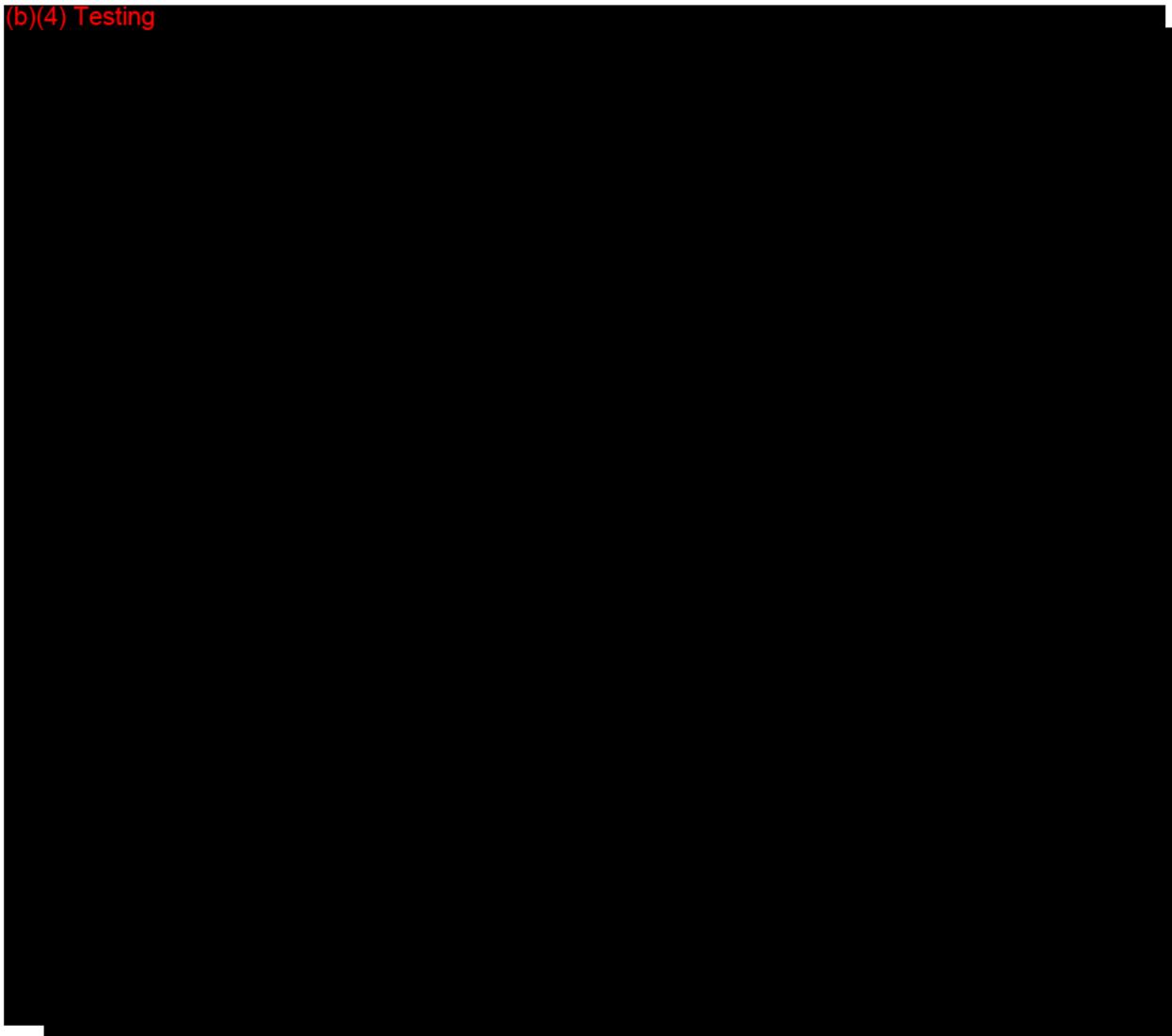
The Biocompatibility testing report (b)(4) of the CPS Excel MediGuide Enabled guidewire is attached in **Appendix 13** and the Biocompatibility ISO Max testing report (b)(4) is attached in **Appendix 14**. The biocompatibility testing report (b)(4) is attached in **Appendix 15**.

A summary of test results are provided in Table 7 below.

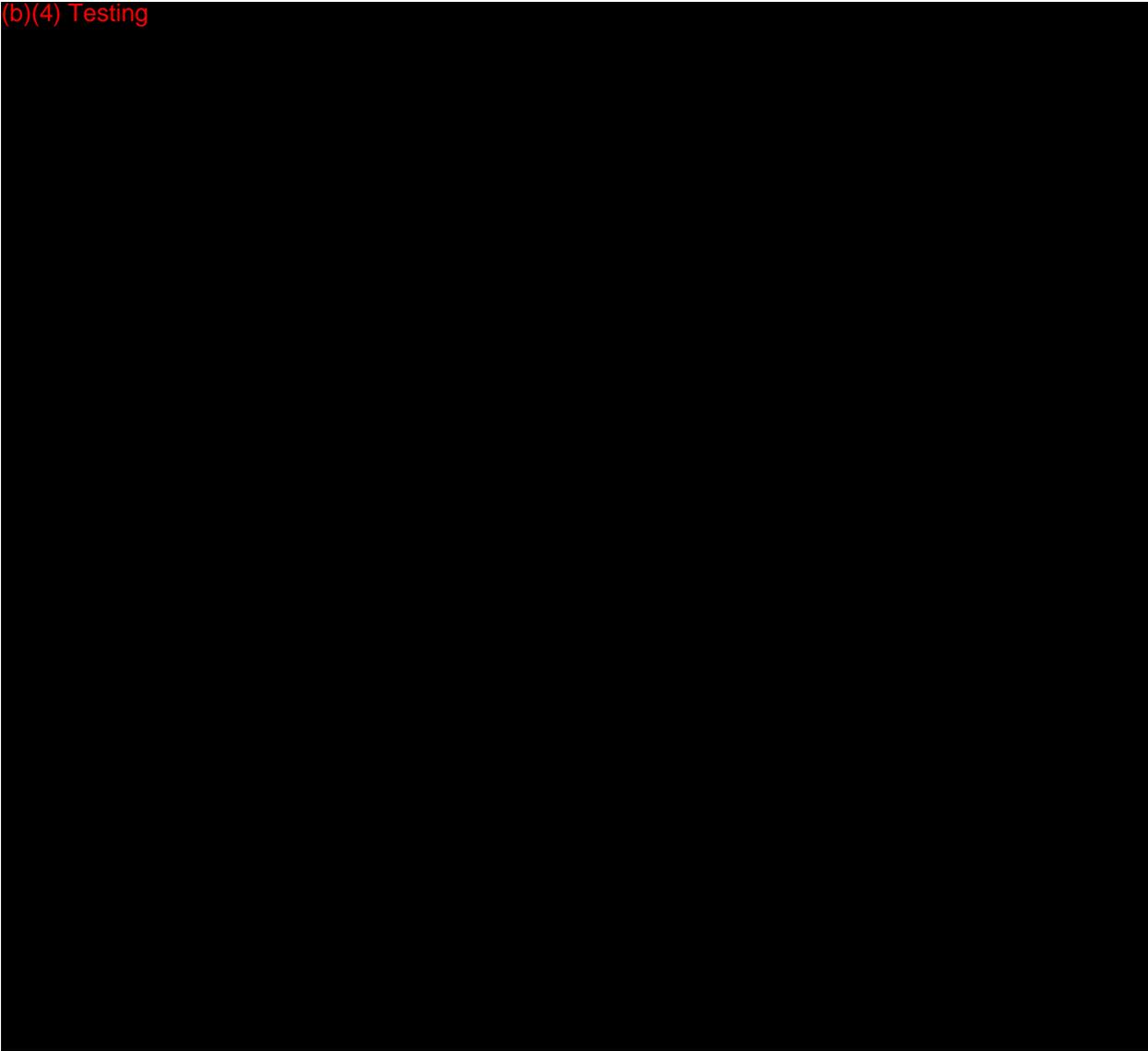
Table 7

Biocompatibility Testing		
Test Description	Acceptance Criteria	Result
(b)(4)		

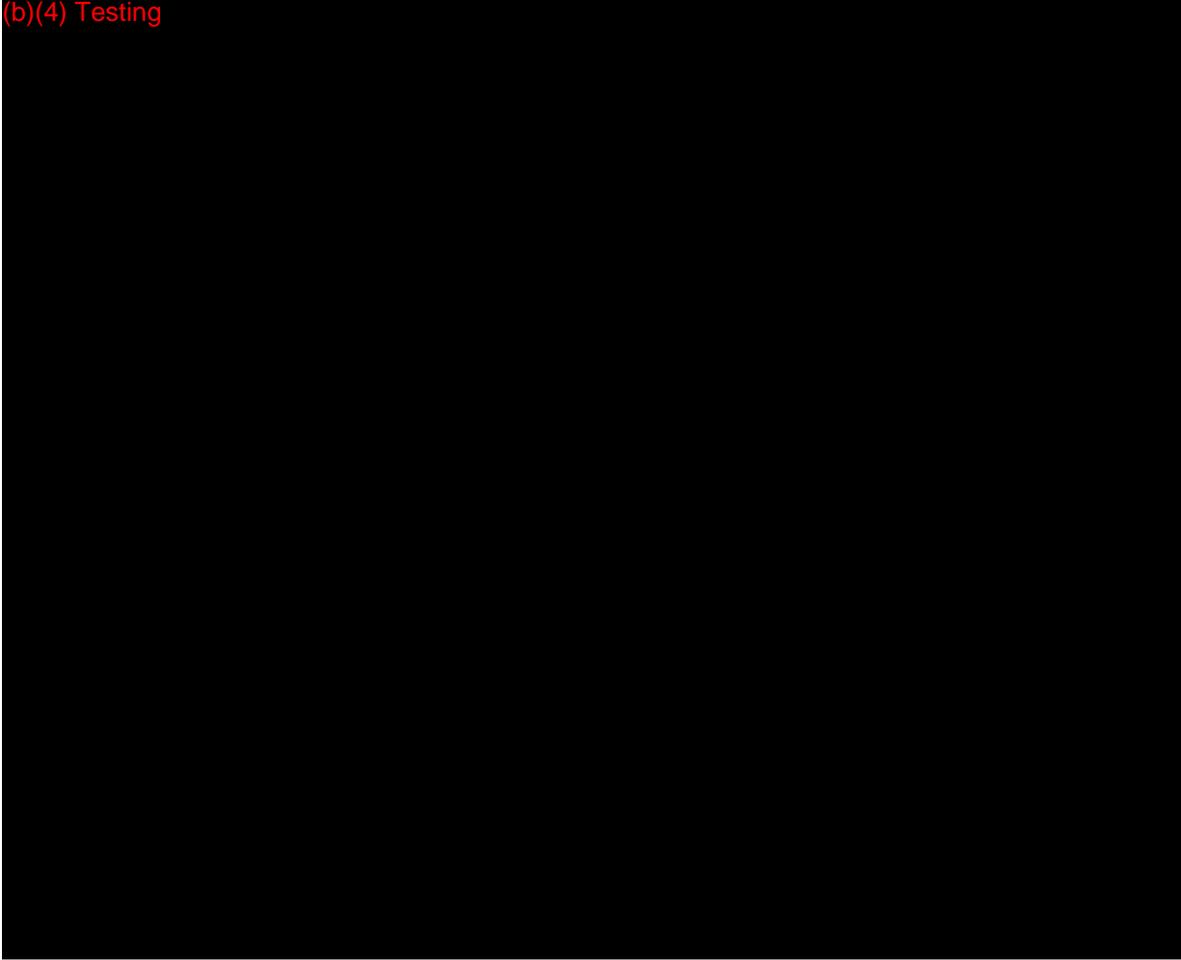
(b)(4) Testing



(b)(4) Testing



(b)(4) Testing



Section 16-Software

The device does not contain software; therefore this section is not applicable

Section 17- Electronic Compatibility and Electrical Safety

This section is not applicable to the CPS Excel MediGuide Enabled guidewire kit

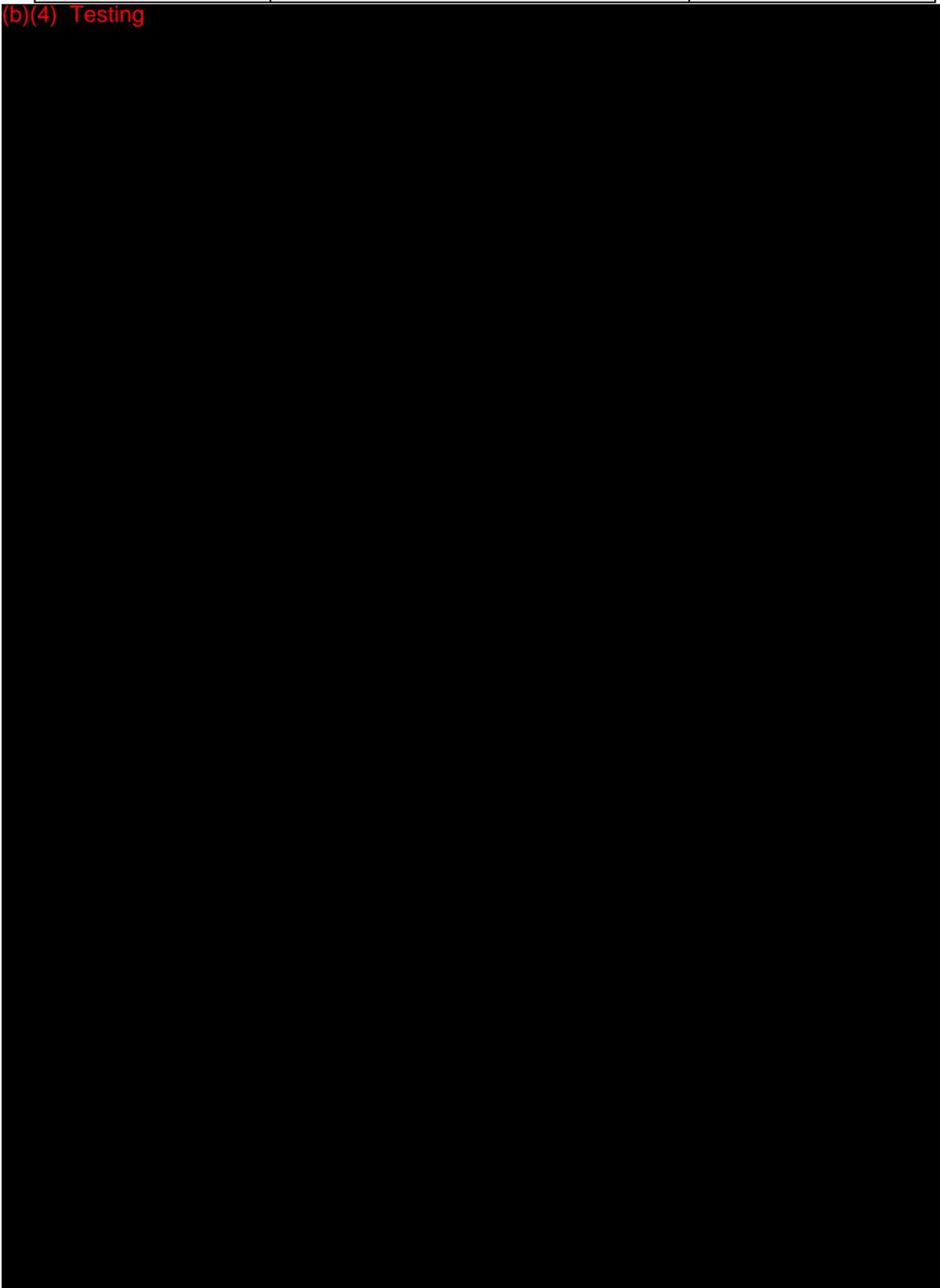
Section 18- Performance Testing- Bench

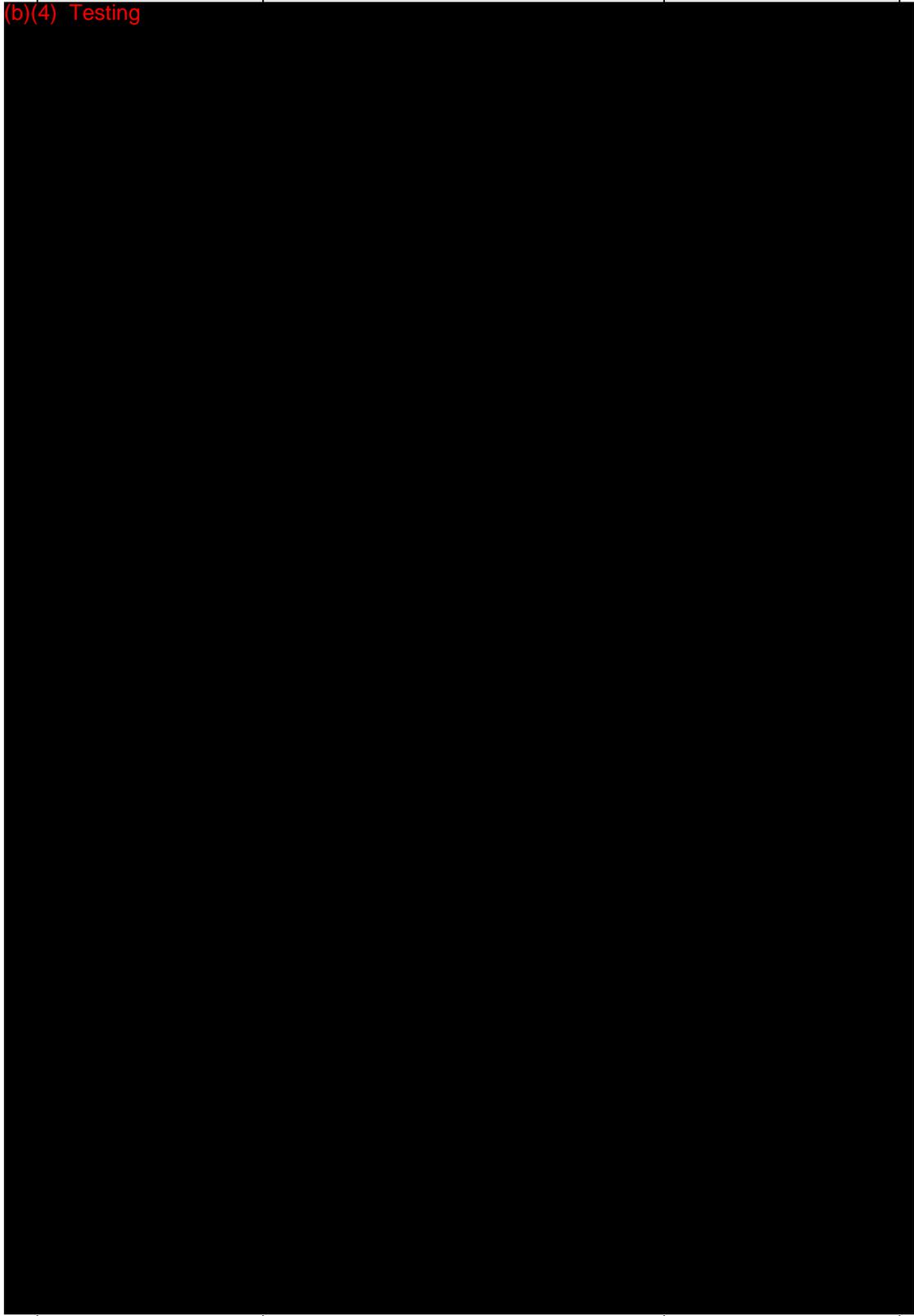
Product verification was performed on the CPS Excel MediGuide Enabled guidewire kit and accessory MediGuide extension cable, guidewire connector and guidewire torque clip to confirm they meet the design requirements and applicable industry standards per product specification numbers 60034961, 60035470, and 60035470. The Functional Verification Report for the CPS Excel MediGuide Enabled guidewire is provided in QTR (b)(4) (Appendix 1) and in QTR (b)(4) (Appendix 2) for the accessory guidewire connector, QTR (b)(4) (Appendix 3) for the guidewire torque clip, and QTR (b)(4) (Appendix 4) for the Mediguide extension cable.

A summary of test results are provided in Table 8

Summary of Tests and Results

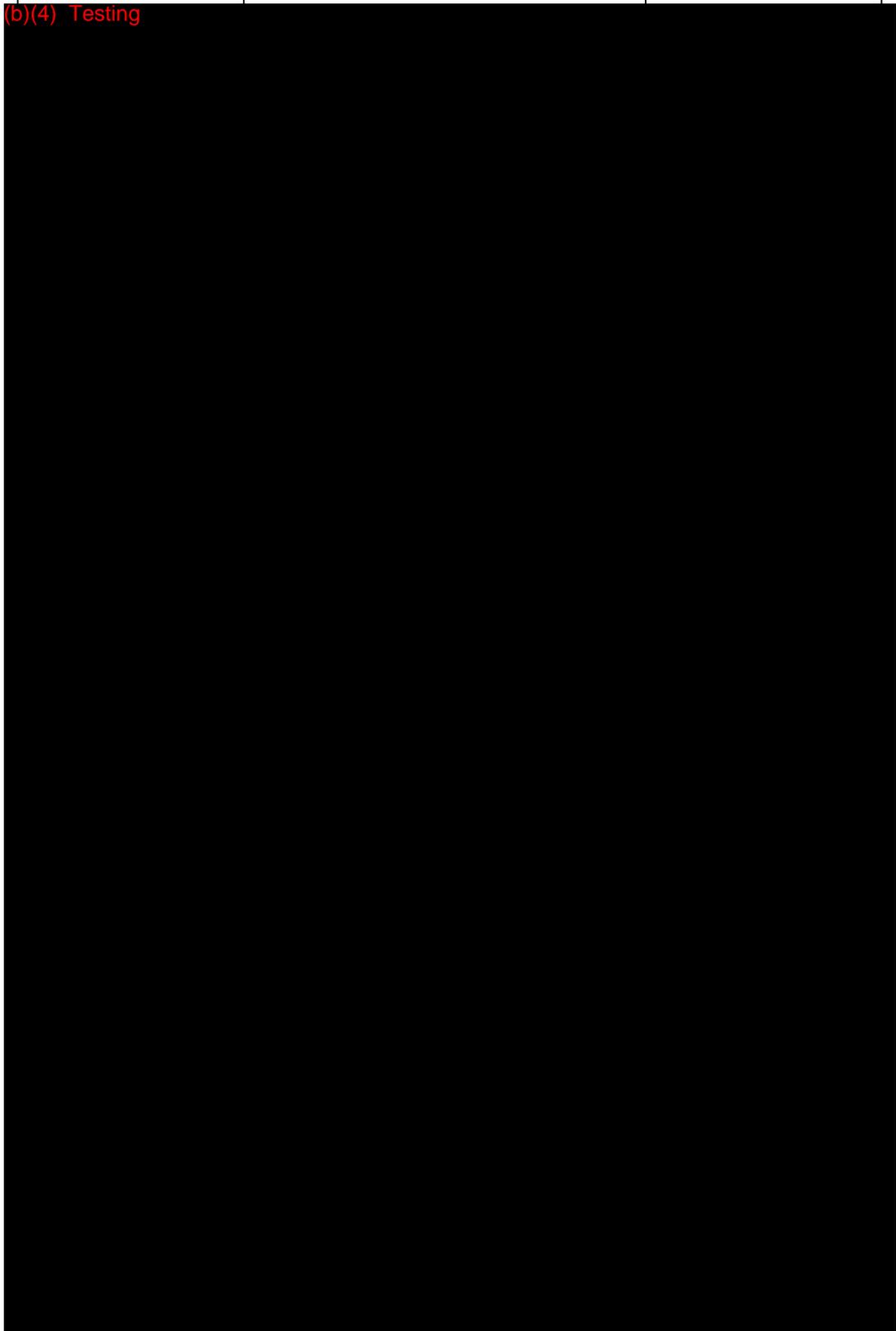
Table 8

Test	Acceptance Criteria	Result
<p>(b)(4) Testing</p> 		

Test	Acceptance Criteria	Result
<p>(b)(4) Testing</p> 		

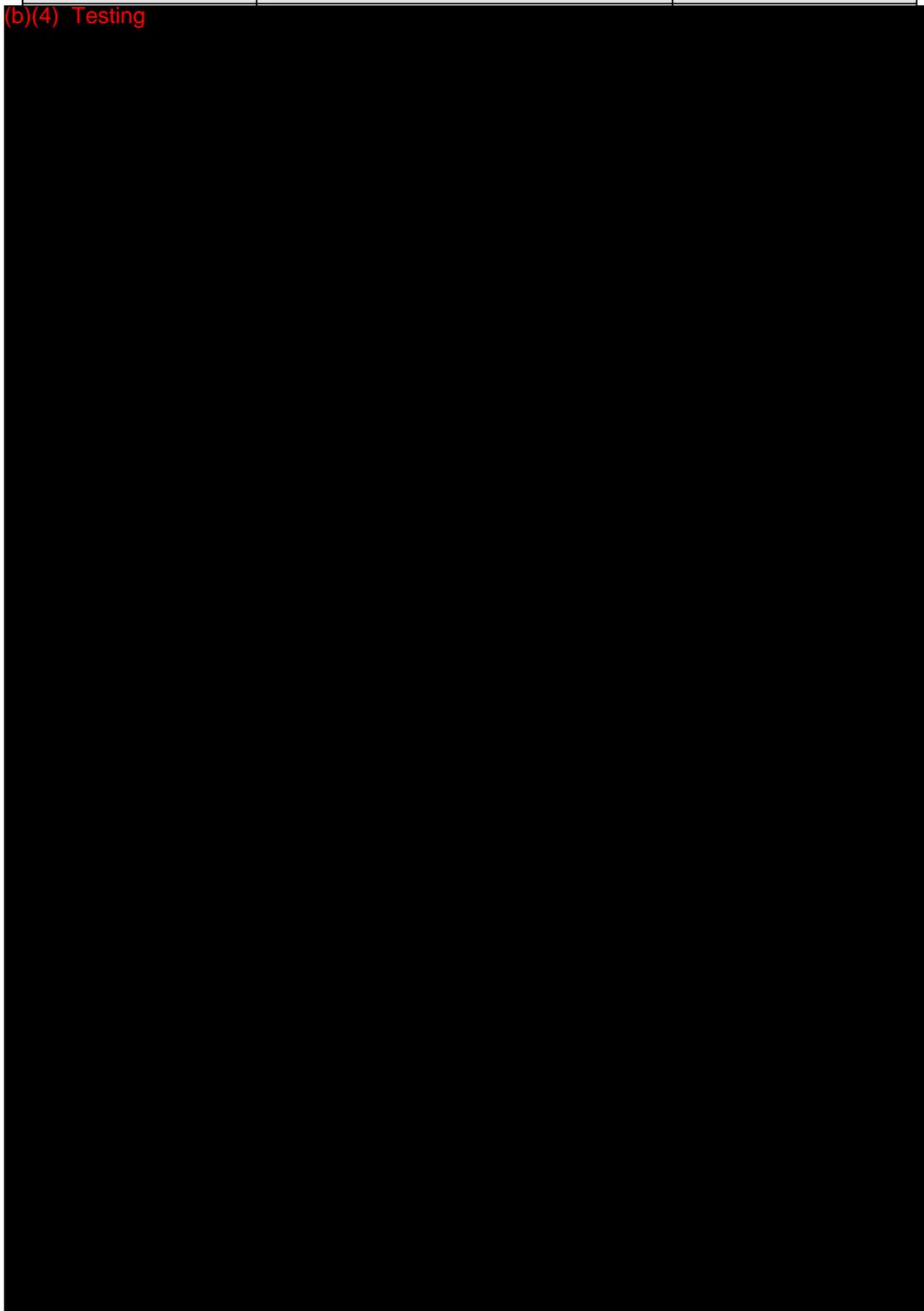
Test	Acceptance Criteria	Result
------	---------------------	--------

(b)(4) Testing



Test	Acceptance Criteria	Result
------	---------------------	--------

(b)(4) Testing



Section 19- Performance Testing- Animal

This section is not applicable to the CPS Excel MediGuide guidewire

Section 20 - Performance Testing- Clinical

No clinical studies were performed in support of the development of this product.

Appendix 1

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: Jan 12, 2012	
		Page 1(56)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report of MediGuide (b)(4)			
Model numbers: DS2M021, DS2M022, DS2M023, DS2M024, DS2M025, DS2M026			
1.0 CONCURRENCE			
Author Name/Title:	Dept:	Signature:	Date:
(b)(6) Design Assurance Engineer	901015	(b)(6)	1/30/2012
Approved by/Title:			
Colleen Canan Regulatory Affairs (US)	744	See Attached	
Approved by/Title:			
(b)(6) Regulatory Affairs (OUS)	743	See Attached	
Approved By/Title:			
(b)(6) Development Engineer	901013	(b)(6)	27 JAN 12
Approved By/Title:			
(b)(6) Program/Development Manager	901013	(b)(6)	27 Jan 2012
Approved By/Title:			
(b)(6) Sr. Manager, QA Operations	105002	See Attached	

(b)(4) QTR - Product Verification Test Report of MediGuide (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: Jan 12, 2012	
		Page 1(56)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR - Product Verification Test Report of MediGuide (b)(4) (b)(4)			
Model numbers: DS2M021, DS2M022, DS2M023, DS2M024, DS2M025, DS2M026			
1.0 CONCURRENCE			
Author Name/Title:	Dept:	Signature:	Date:
(b)(6) Design Assurance Engineer	901015		
Approved by/Title:			
Colleen Canan Regulatory Affairs (US)	744	<i>Colleen Canan</i>	25-JAN-2012
Approved by/Title:			
(b)(6) Regulatory Affairs (OUS)	743		
Approved By/Title:			
(b)(6) Development Engineer	901013		
Approved By/Title:			
(b)(6) Program/Development Manager	901013		
Approved By/Title:			
(b)(6) Sr. Manager, QA Operations	105002		

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: Jan 12, 2012	
		Page 1(56)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title:			
QTR – Product Verification Test Report of MediGuide (b)(4)			
(b)(4)			
Model numbers: DS2M021, DS2M022, DS2M023, DS2M024, DS2M025, DS2M026			
1.0 CONCURRENCE			
Author Name/Title:	Dept:	Signature:	Date:
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Design Assurance Engineer			
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(b)(6)	901013		
Program/Development Manager			
Approved By/Title:			
(b)(6)	105002		
Sr. Manager, QA Operations			

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: Jan 12, 2012	
		Page 1(56)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report of MediGuide (b)(4)			
(b)(4)			
Model numbers: DS2M021, DS2M022, DS2M023, DS2M024, DS2M025, DS2M026			
1.0 CONCURRENCE			
Author Name/Title:	Dept:	Signature:	Date:
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(b)(6)	901013		
Program/Development Manager			
Approved By/Title:		(b)(6)	
(b)(6)	105002		1/30/12
Sr. Manager, QA Operations			

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(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

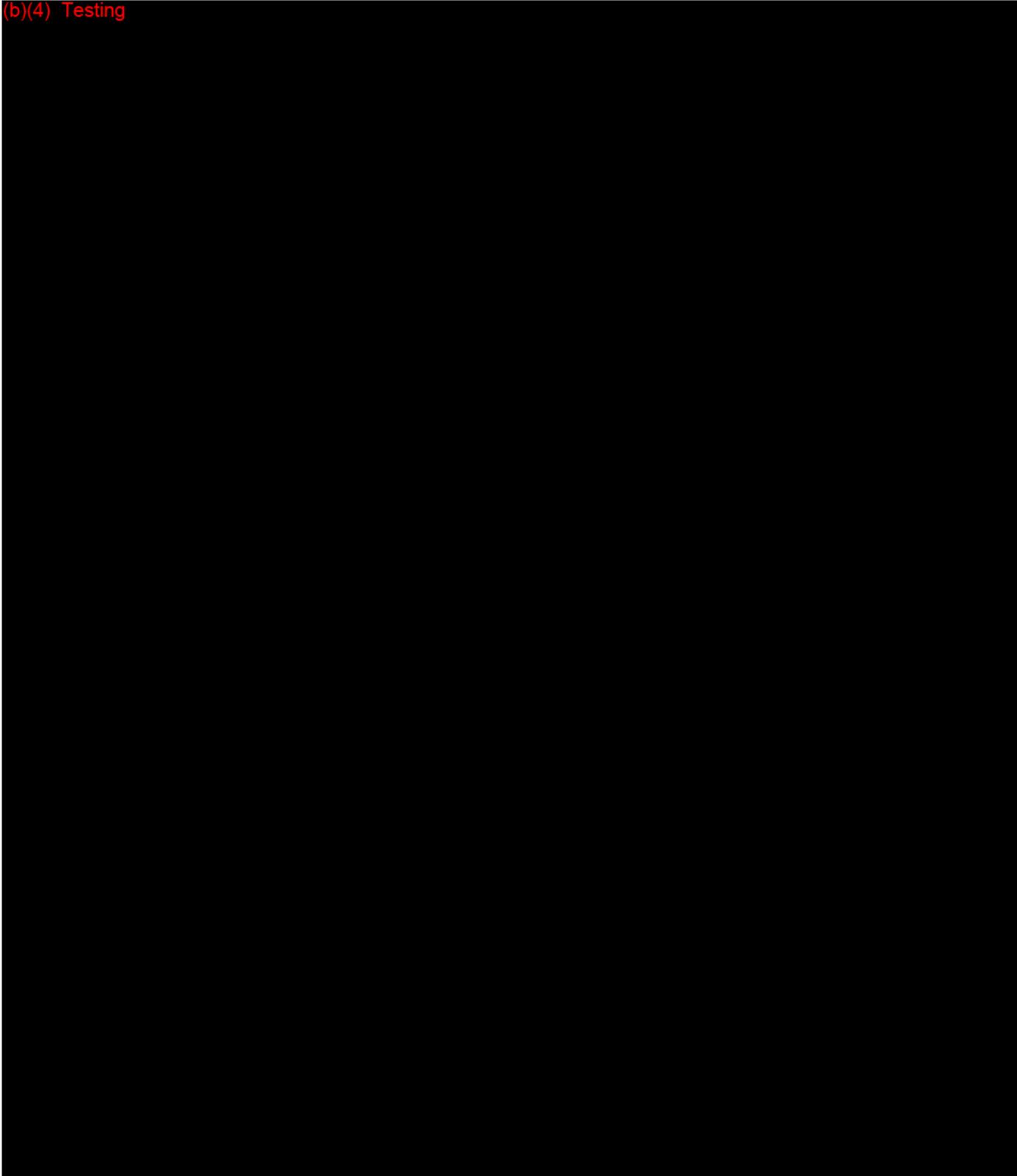
(b)(4) Date: Jan 12, 2012
QTR – Product Verification Test Report of MediGuide (b)(4)
(b)(4)
Model numbers: DS2M021, DS2M022, DS2M023, DS2M024, DS2M025, DS2M026

3.0 PURPOSE

(b)(4)

(b)(4) Testing

(b)(4) Testing



(b)(4)

(b)(4) Testing

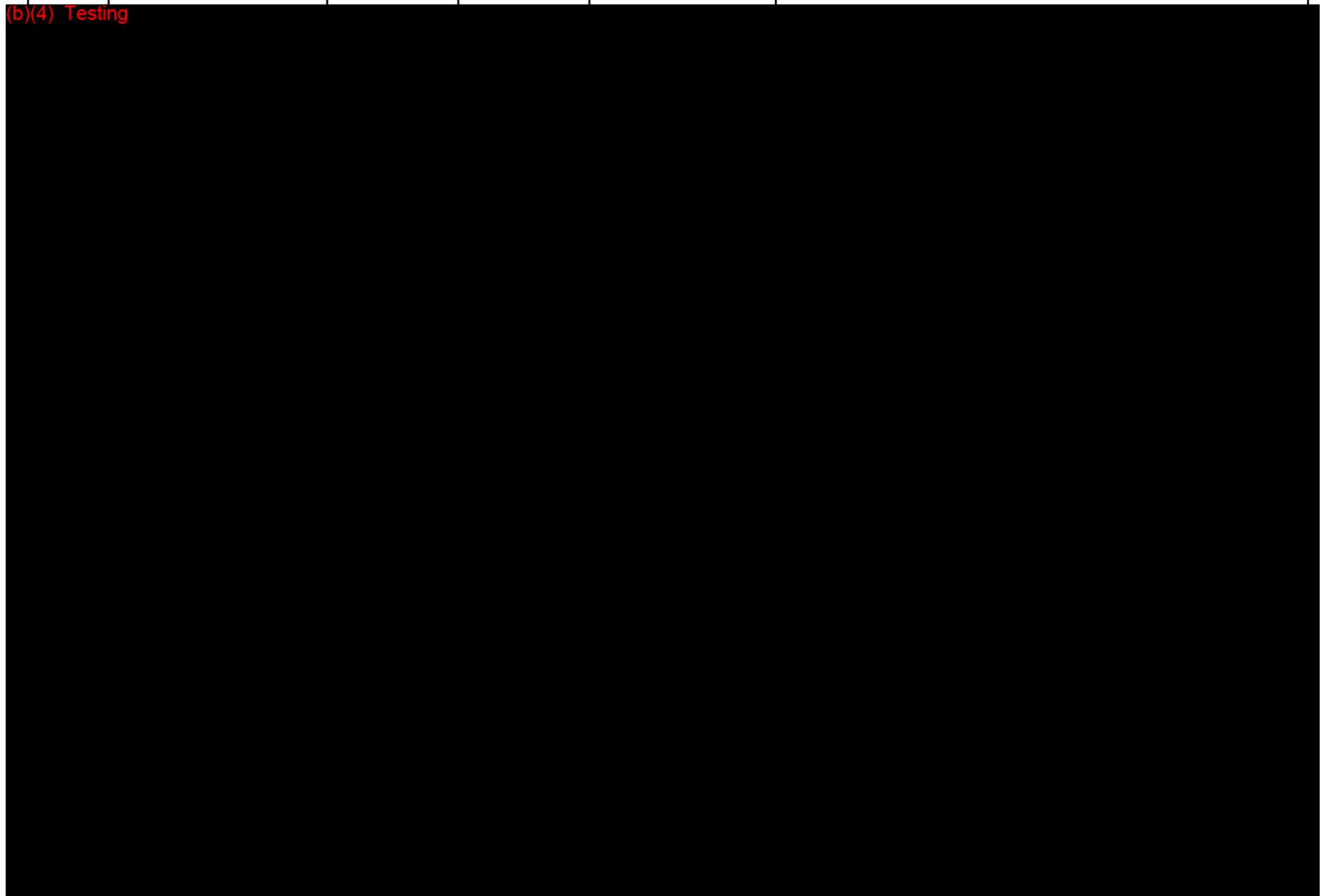
Table 3 Tests Included in this Report

Test		Model Tested	Requirement/ Specification	Rationale
(b)(4)				
(b)(4) Testing				

(b)(4)

QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4) Testing



Company Confidential

7(56)

Design Assurance

(b)(4)

QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4) Testing



Company Confidential

8(56)

Design Assurance

(b)(4)

QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4) Testing

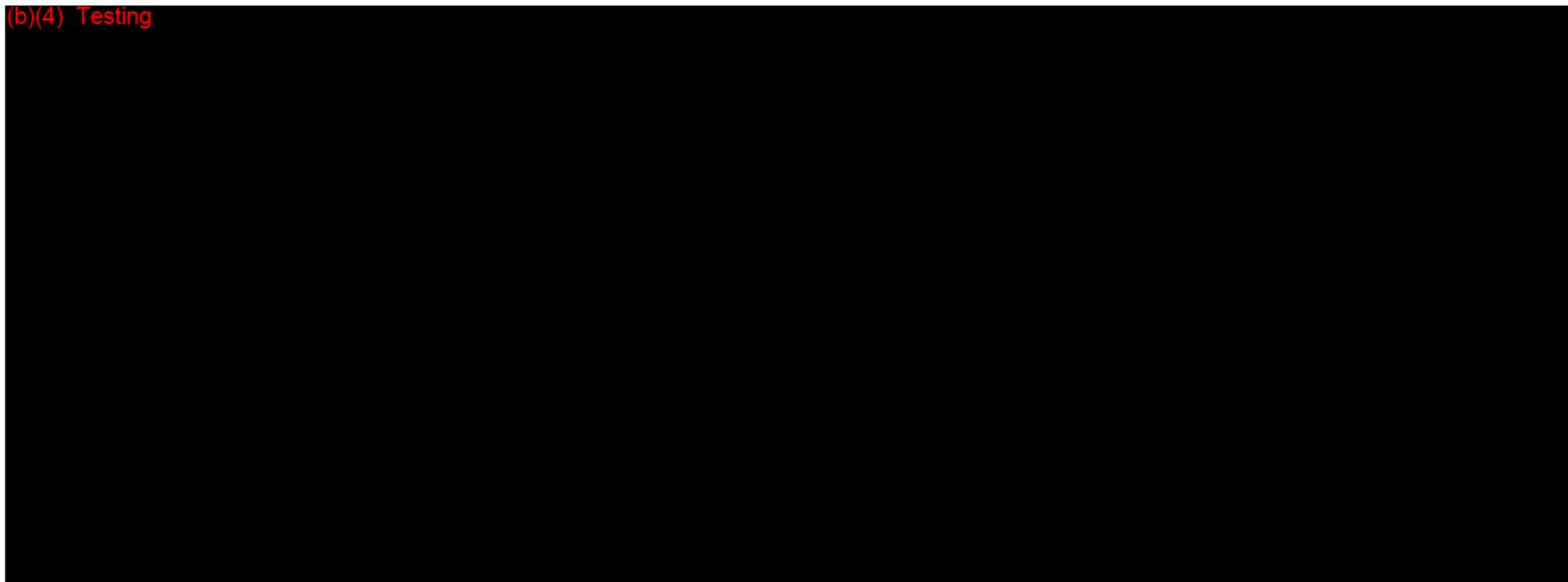
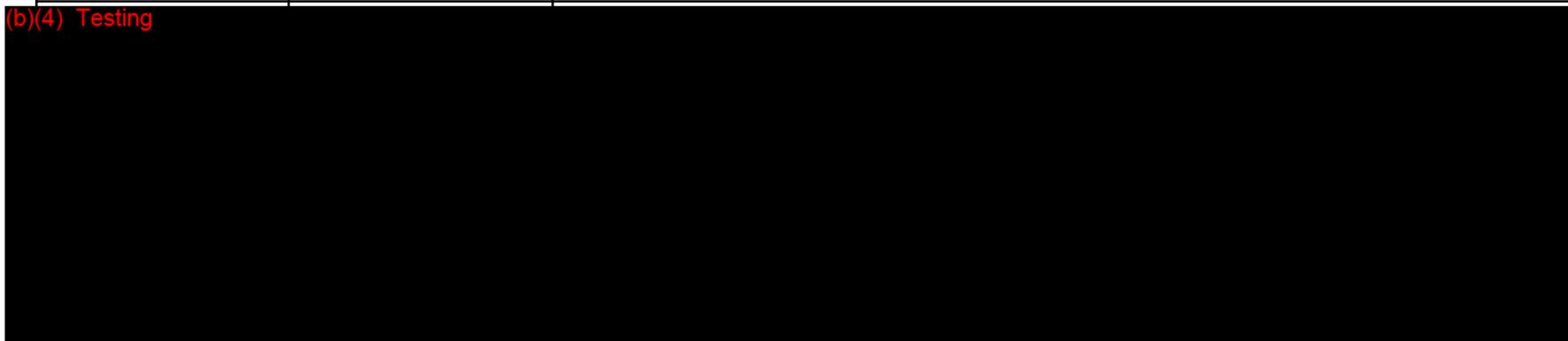


Table 4 Tests Excluded from this Report

Test	Requirement/ Specification	Rationale
------	-------------------------------	-----------

(b)(4) Testing



 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>	Company Confidential	9(56)	Design Assurance
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(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4) Testing

4.1 SUMMARY OF RESULTS

(b)(4) Testing

Table 5 Summary of Results

Test #	Test	Failures	Analysis & Corrective Actions
--------	------	----------	-------------------------------

(b)(4) Testing

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

Test #	Test	Failures	Analysis & Corrective Actions
(b)(4) Testing			

4.2 CONCLUSIONS

(b)(4) Testing

5.0 ASSOCIATED DOCUMENTS

	Document #	Rev #*	Document Title
5.1	(b)(4)	Testing	
5.2			
5.3			
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			
5.10			
5.11			
5.12			
5.13			
5.14			
5.15			
5.16			
5.17			
5.18			

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

	Document #	Rev #*	Document Title
(b)(4) Testing			

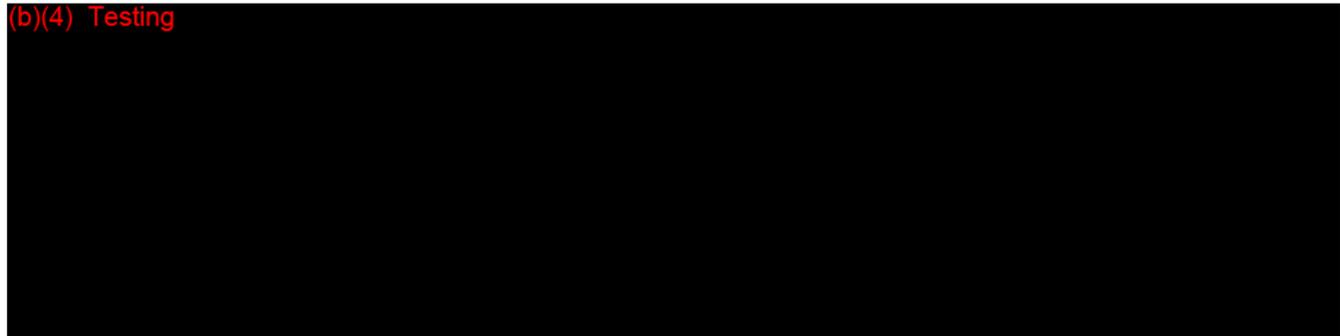
6.0 ASSOCIATED TEST EQUIPMENT

Table 6 Associated Test Equipment

	Description	Applicable Tests
(b)(4) Testing		

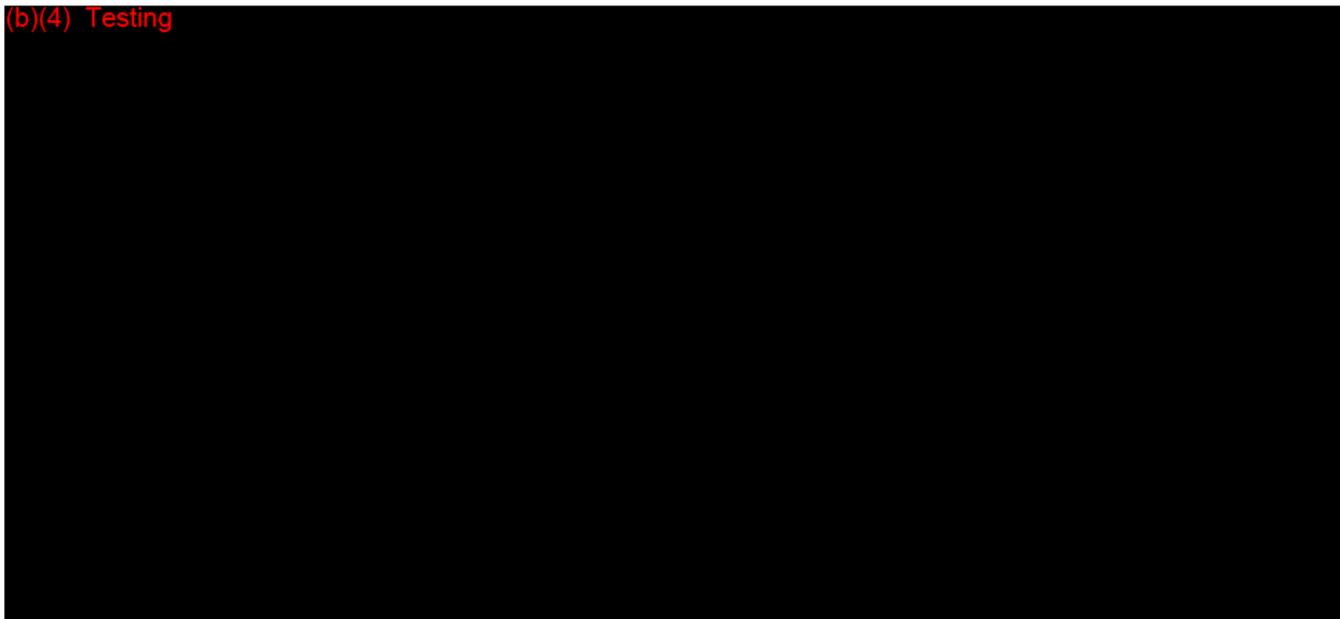
7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4) Testing



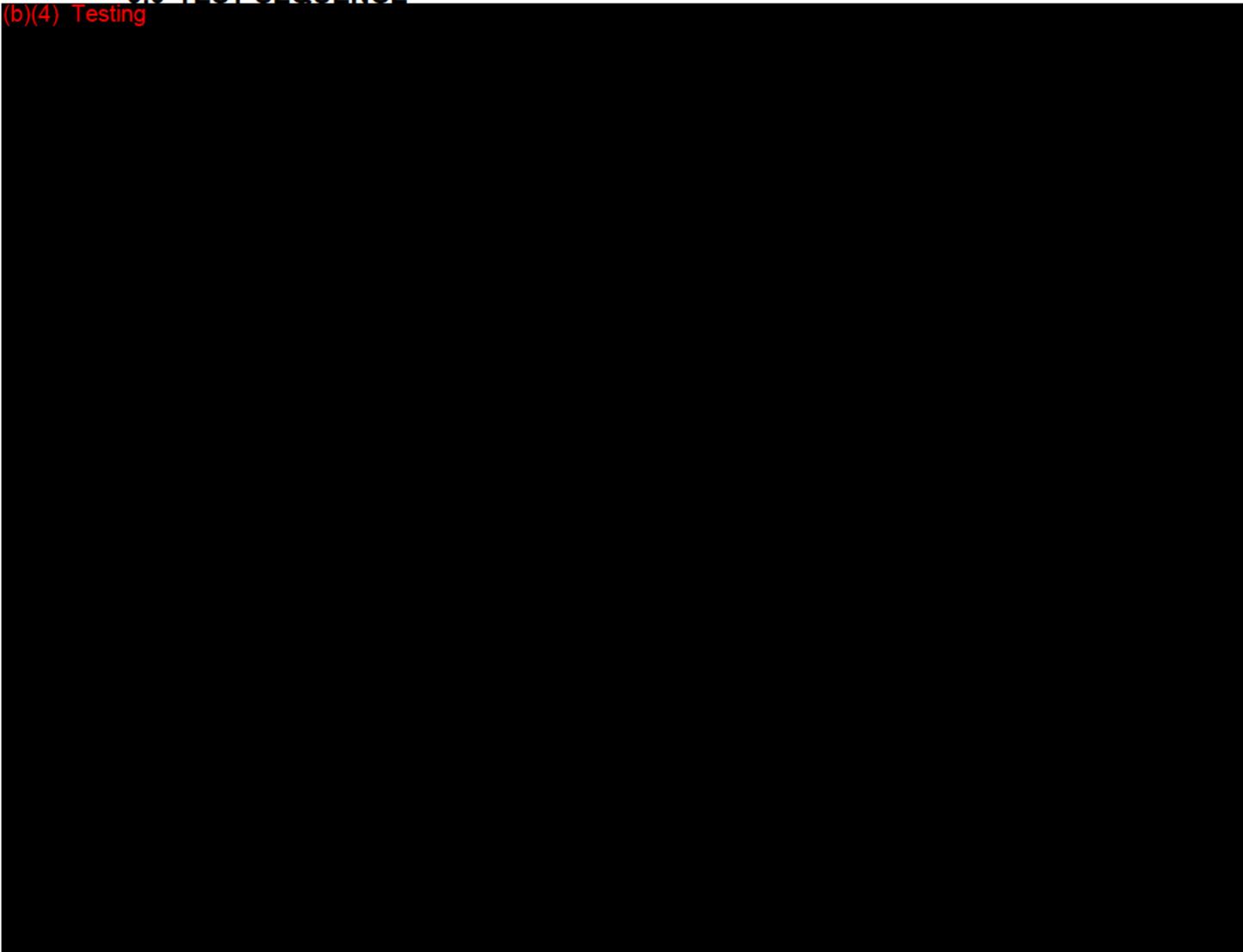
8.0 SAMPLE SIZE JUSTIFICATION

(b)(4) Testing



9.0 TEST SEQUENCE

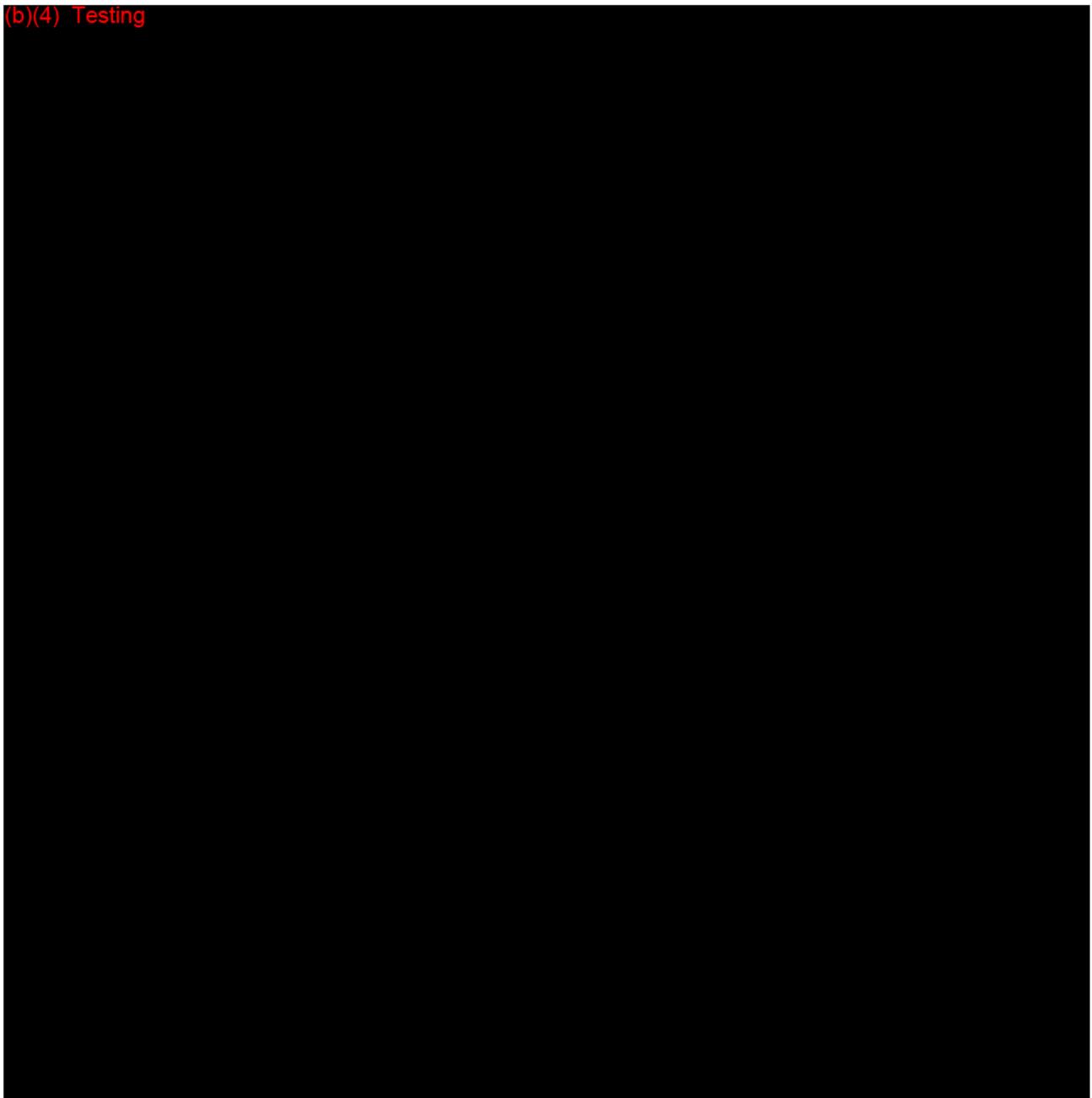
(b)(4) Testing



(b)(4) Testing



(b)(4) Testing



(b)(4) Testing



10.25 Document Compliance

10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4) Testing

TEST RESULTS

(b)(4) Testing

10.2 (b)(4) TEST

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4) Testing

TEST RESULTS

(b)(4) Testing

10.3 (b)(4) Testing TEST

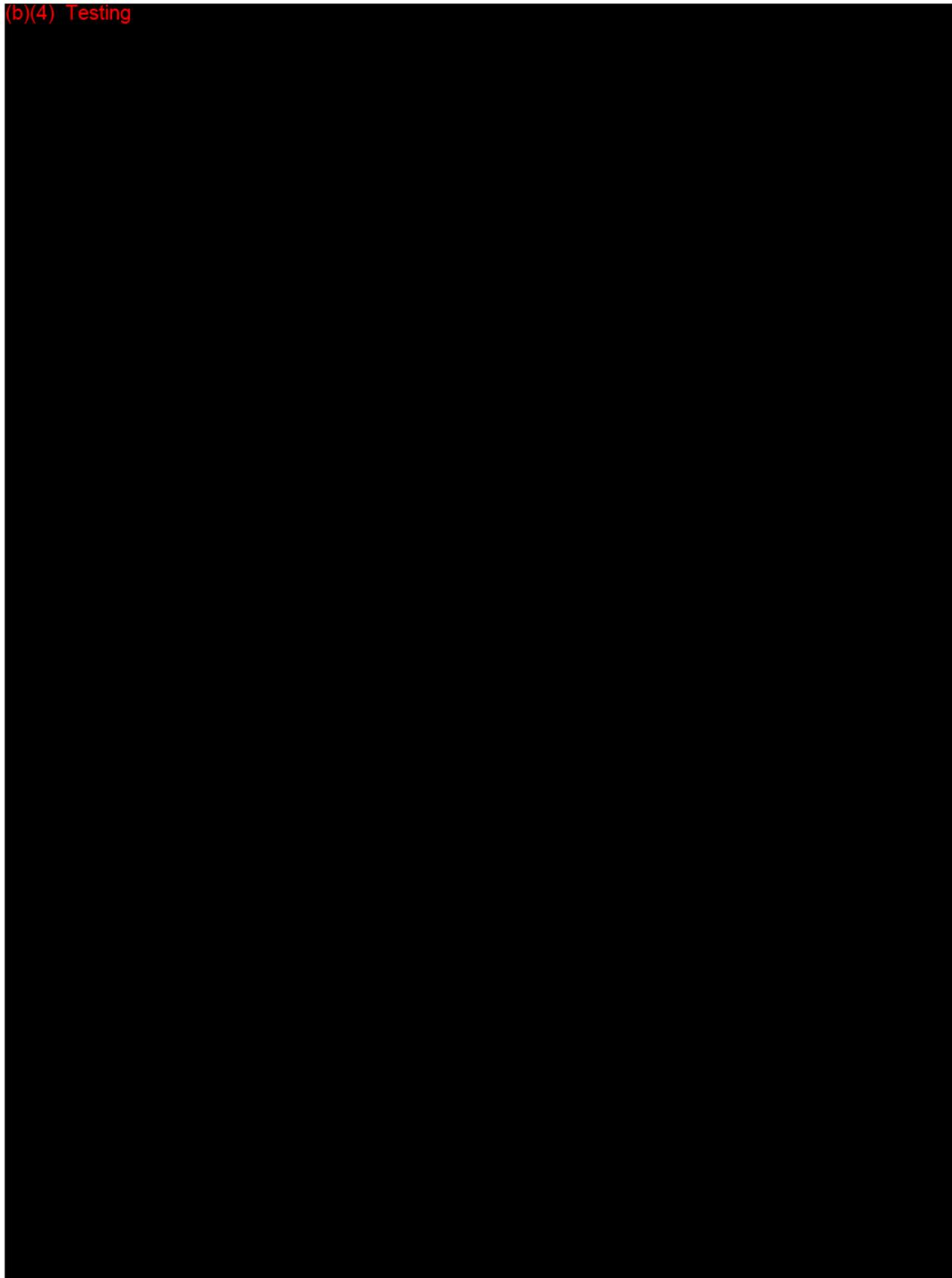
PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

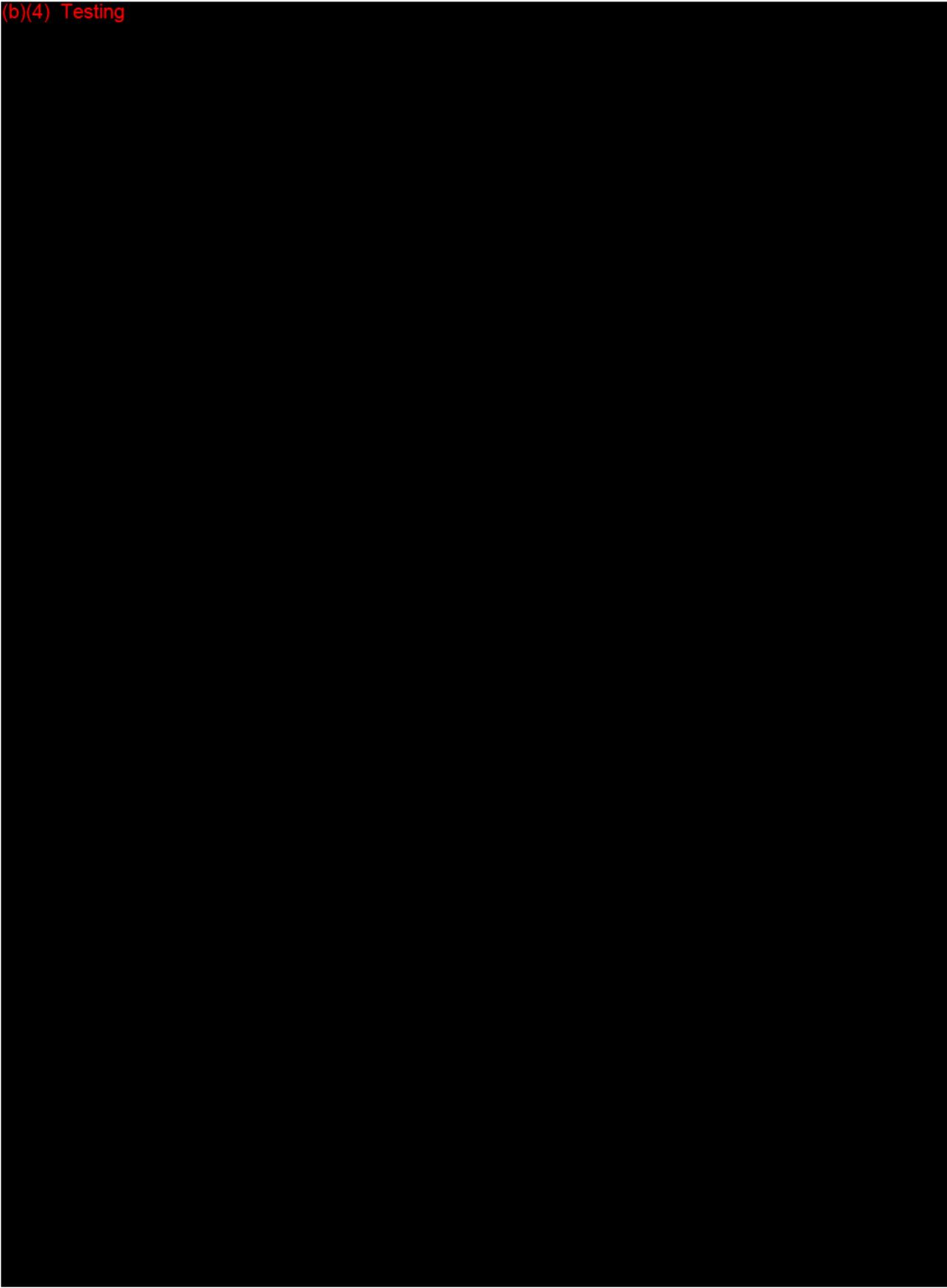
(b)(4) Testing



(b)(4)

QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4) Testing



Company Confidential

22(56)

Design Assurance

(b)(4)



10.5 **(b)(4)** TEST

PURPOSE

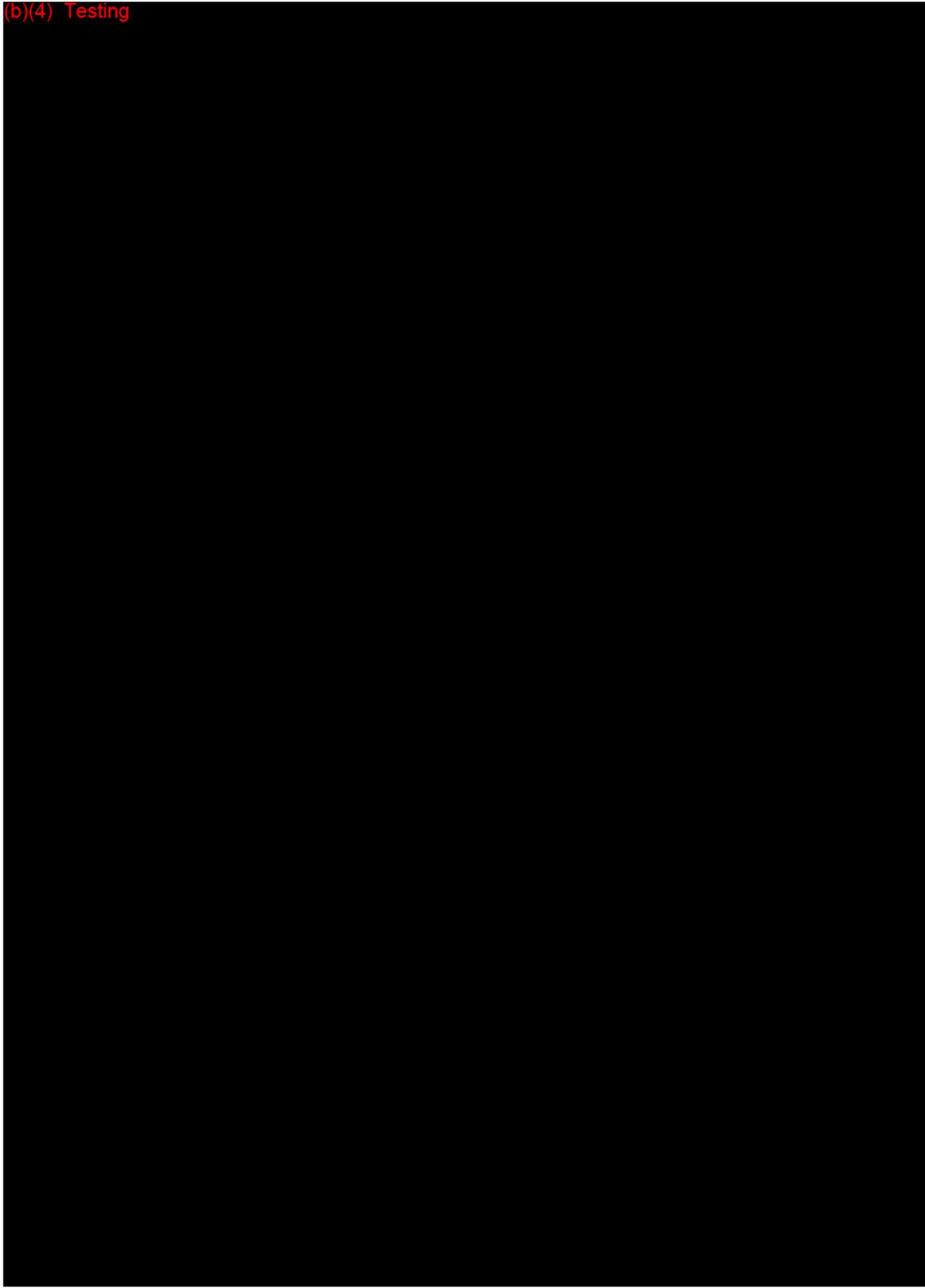
(b)(4)

TEST REQUIREMENT

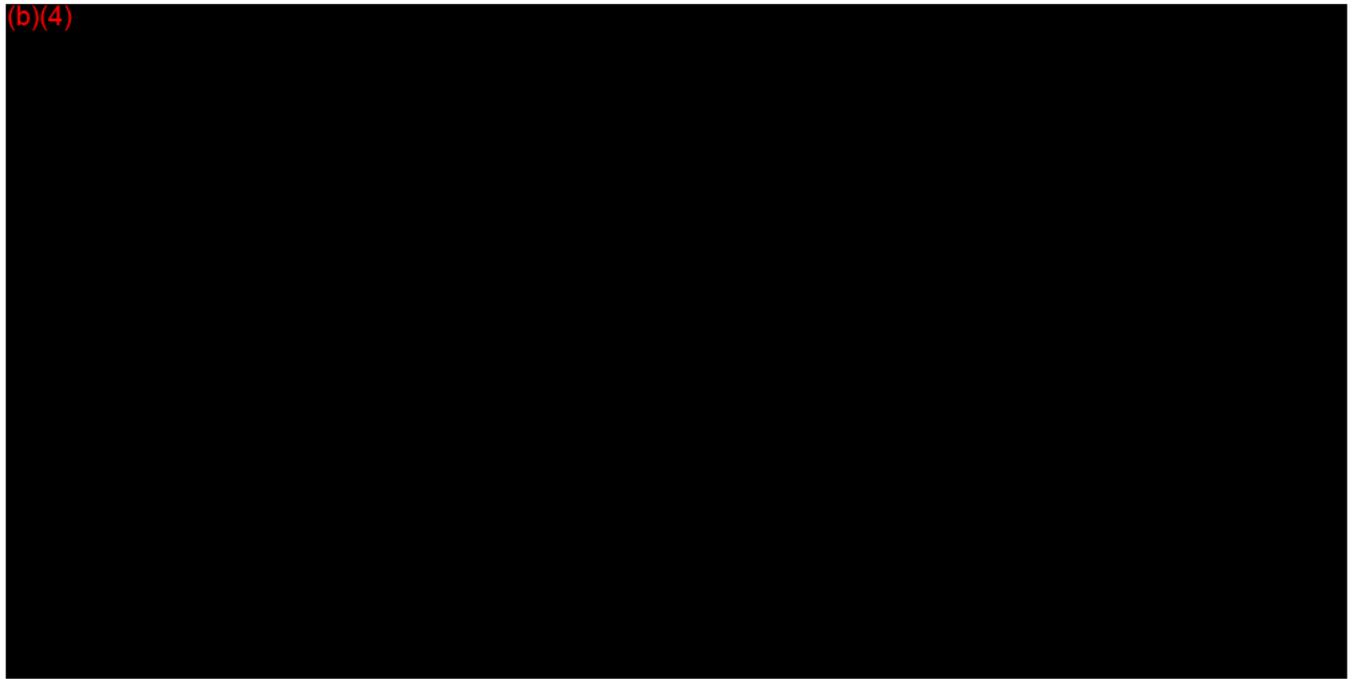
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(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4) Testing

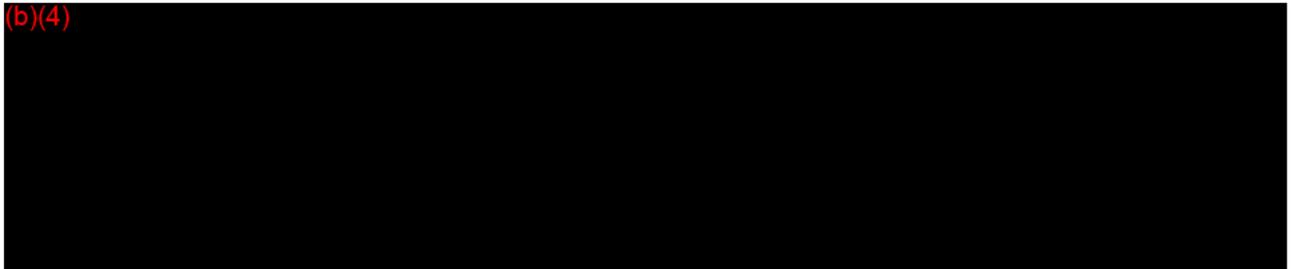


(b)(4)



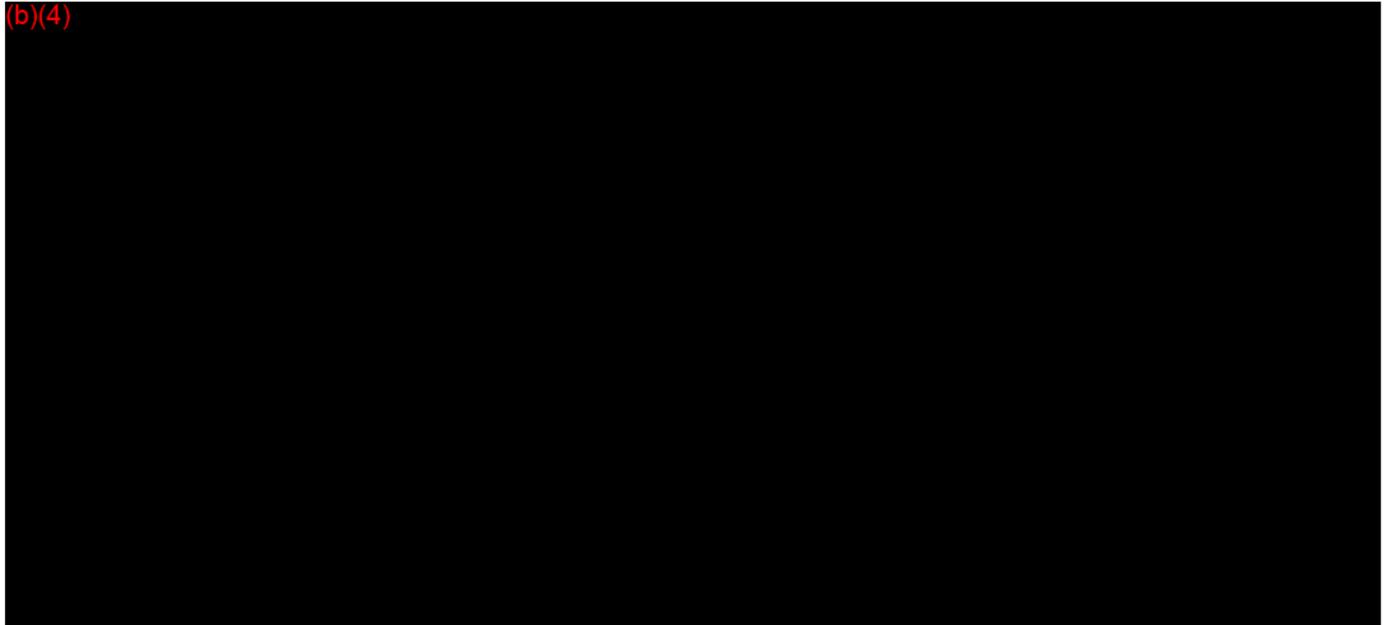
ACCEPTANCE CRITERIA

(b)(4)



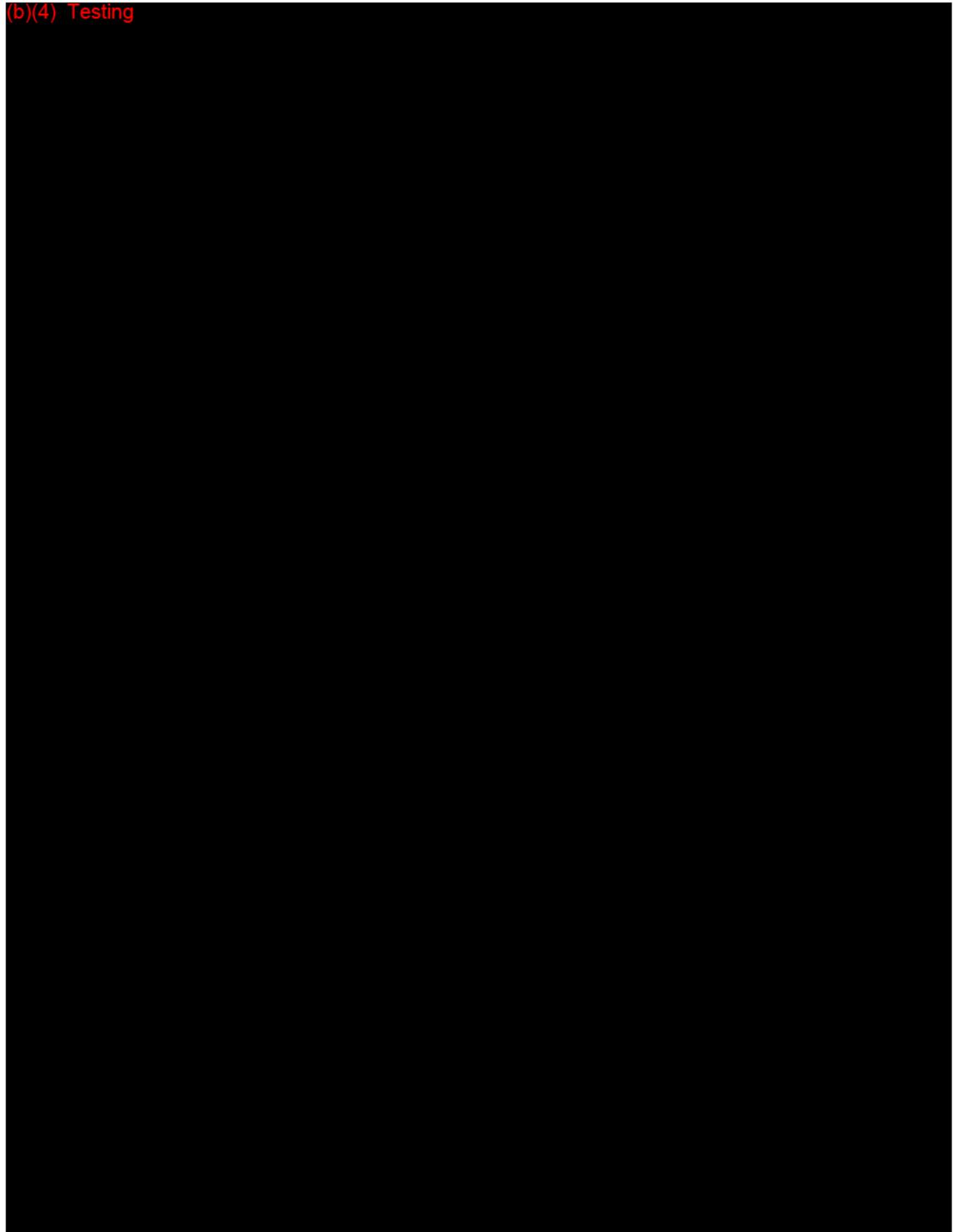
TEST RESULTS

(b)(4)



(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4) Testing



(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

10.6 (b)(4) TEST

PURPOSE

(b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.7 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

10.8 (b)(4) TEST

PURPOSE

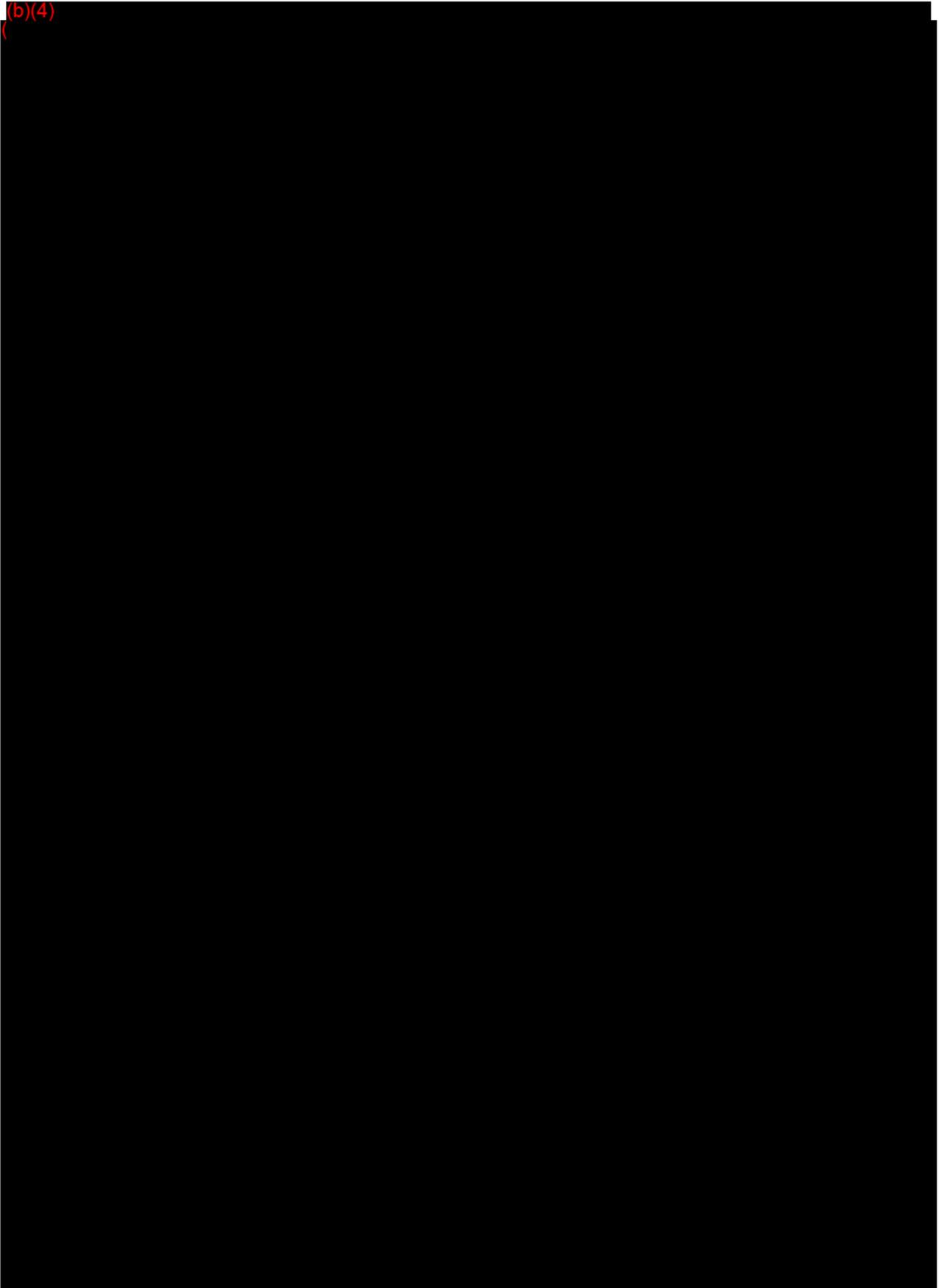
(b)(4)

(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)



Company Confidential

30(56)

Design Assurance

(b)(4)

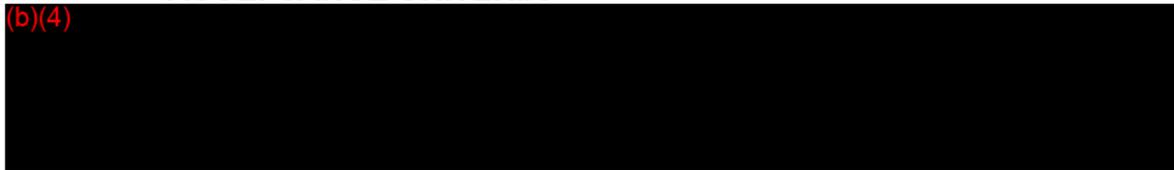
QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)



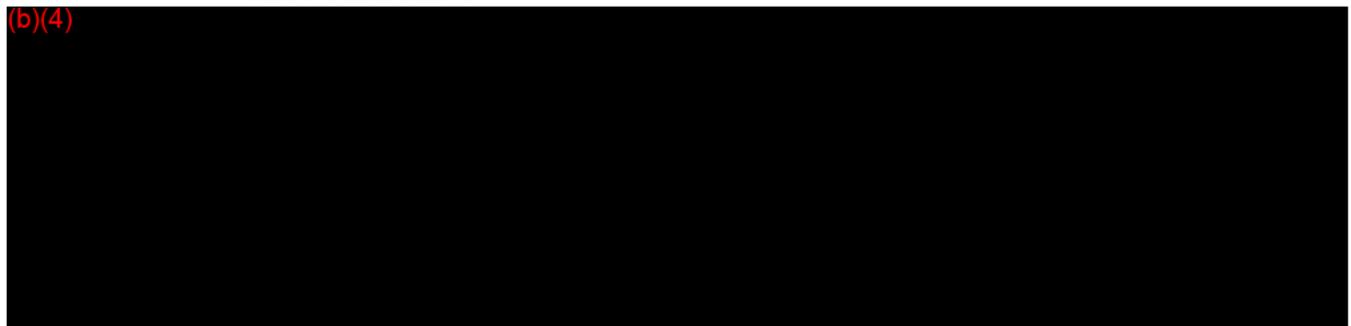
ACCEPTANCE CRITERIA

(b)(4)



TEST RESULTS

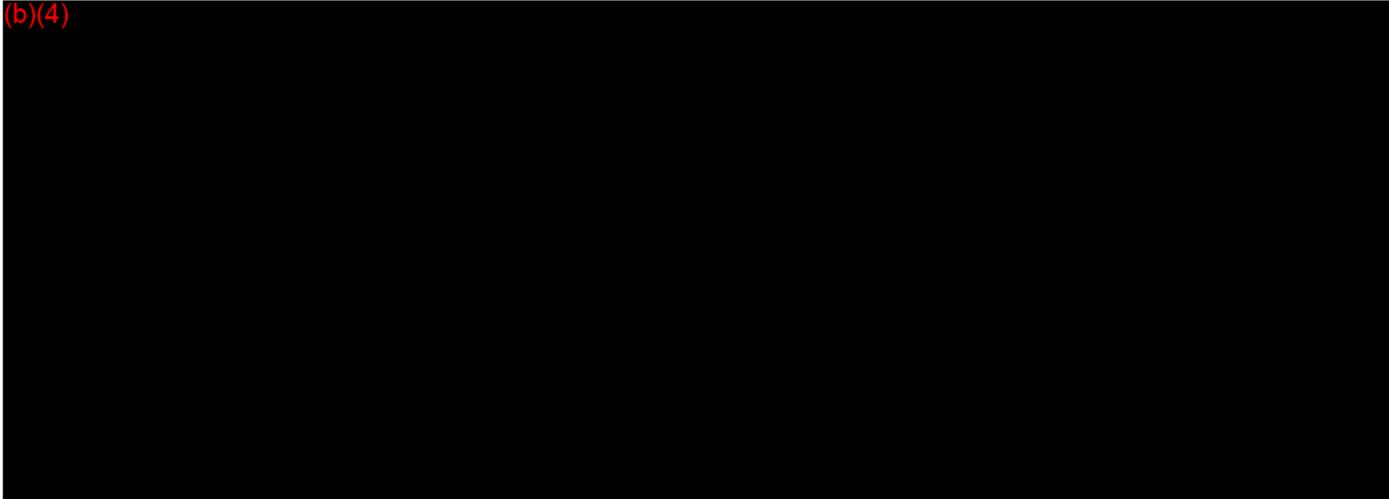
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(b)(4)

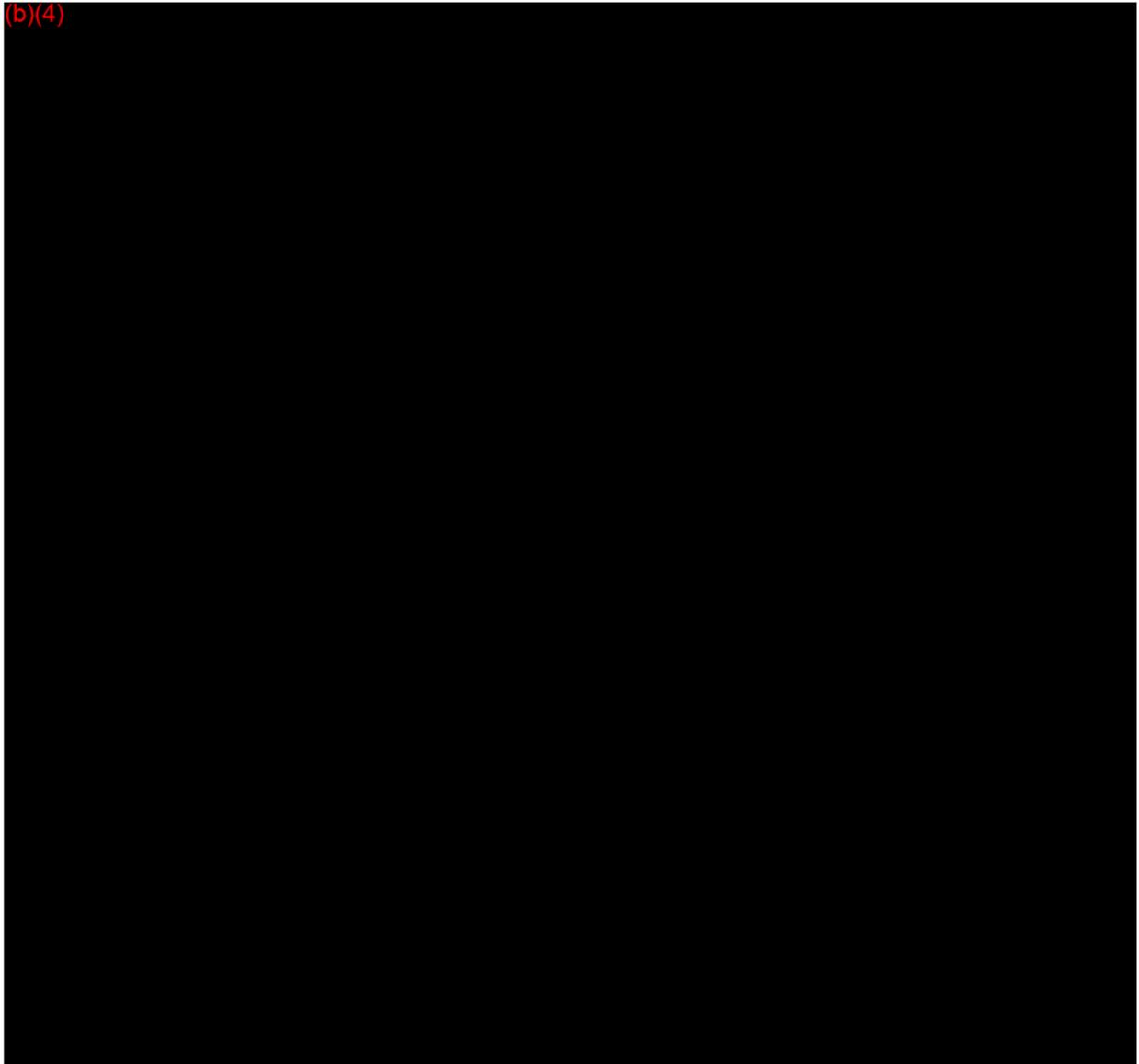
QTR – Product Verification Test Report of MediGuide (b)(4)

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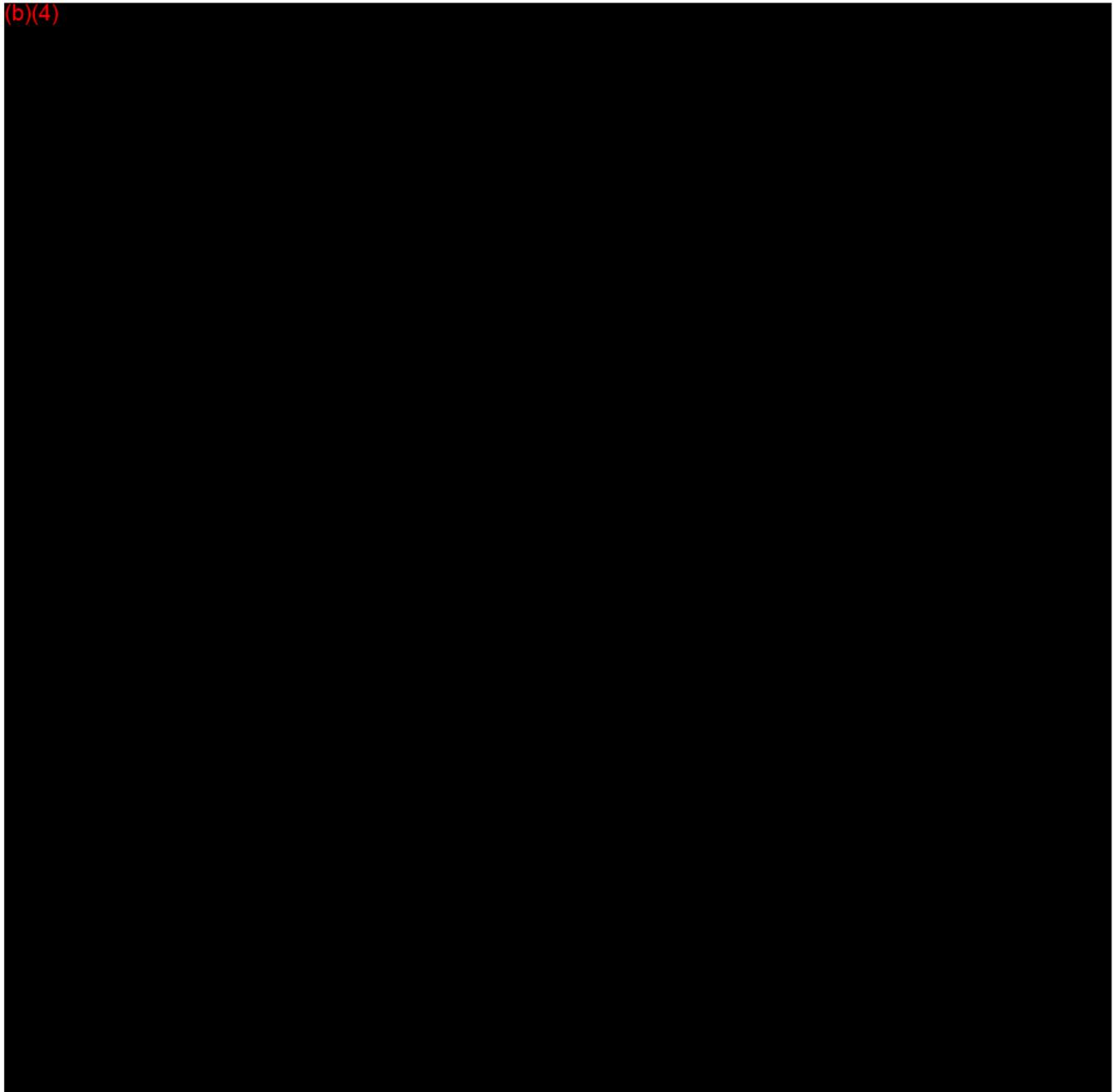


ANALYSIS

(b)(4)



(b)(4)



10.9 (b)(4) TEST

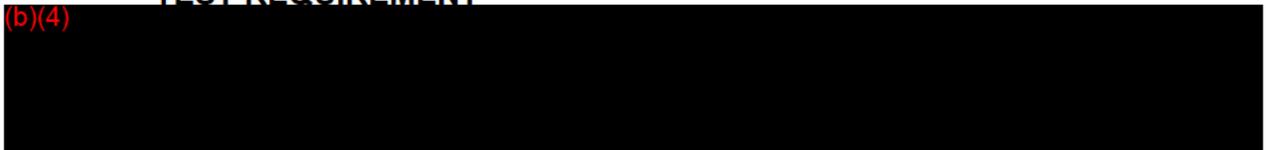
PURPOSE

(b)(4)



TEST REQUIREMENT

(b)(4)



(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.10 (b)(4) TEST

PURPOSE

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

ANALYSIS

(b)(4)

10.11 (b)(4) TEST

PURPOSE

(b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.12 (b)(4)

PURPOSE

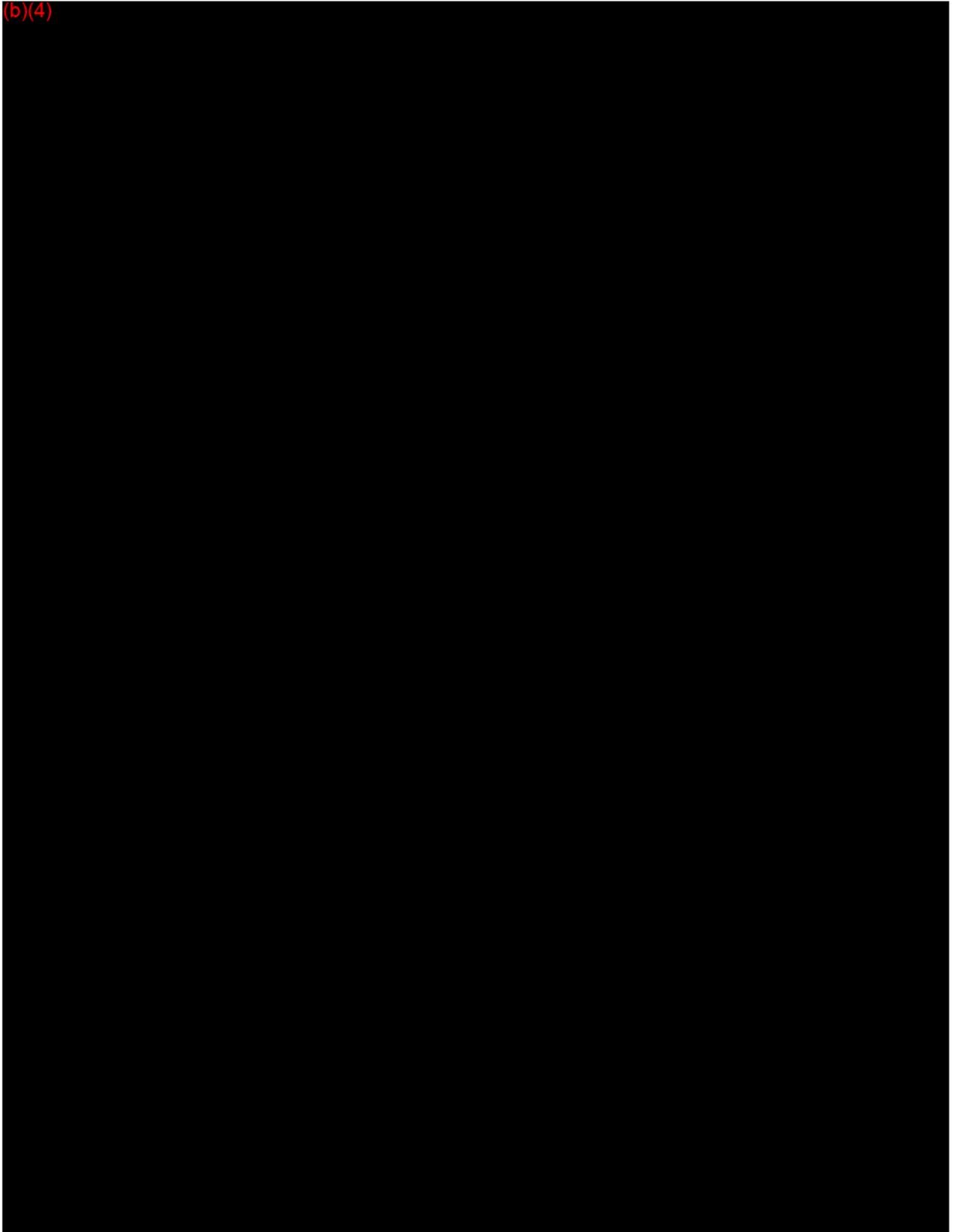
(b)(4)

TEST REQUIREMENT

(b)(4)

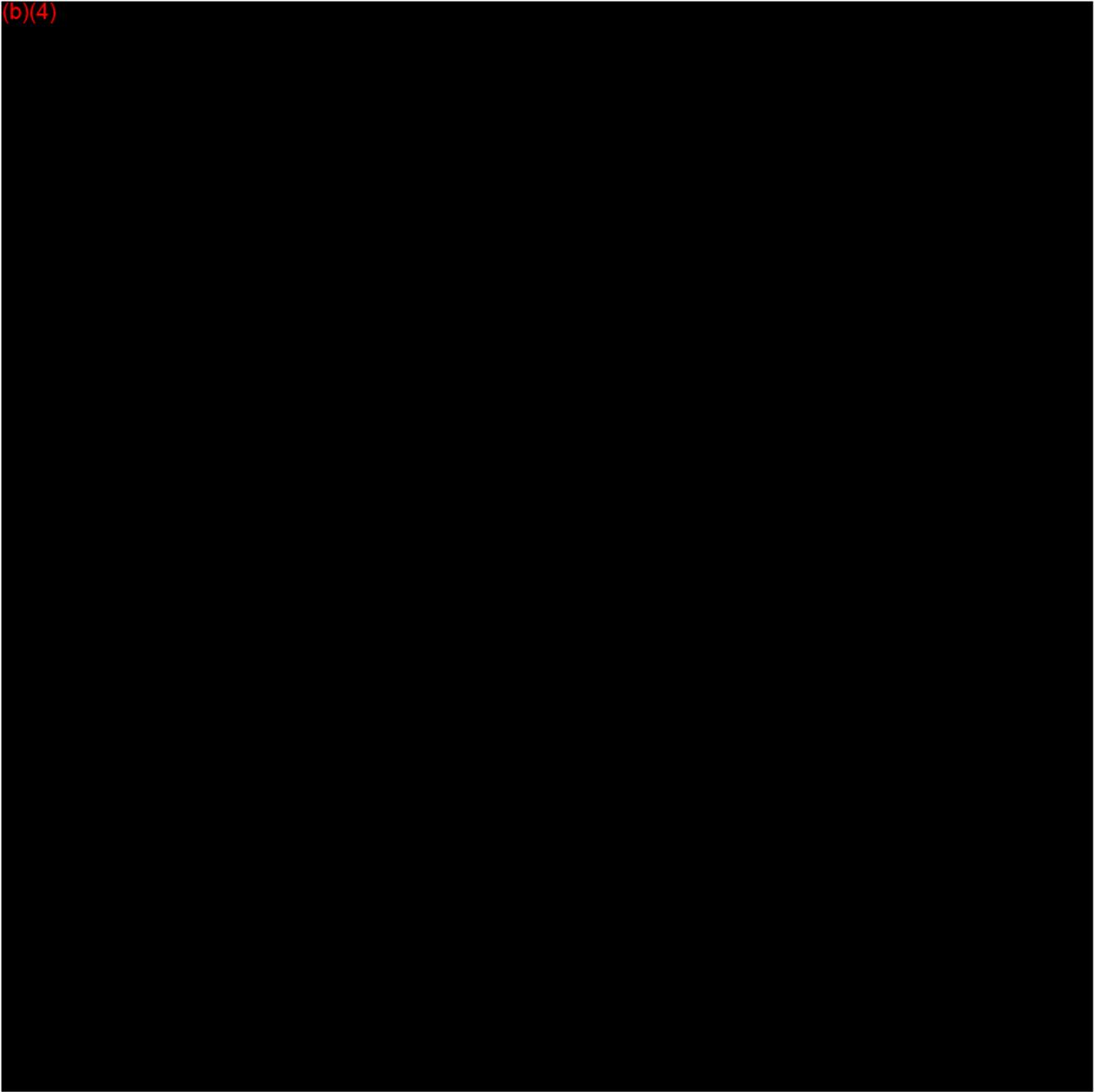
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(b)(4)



(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

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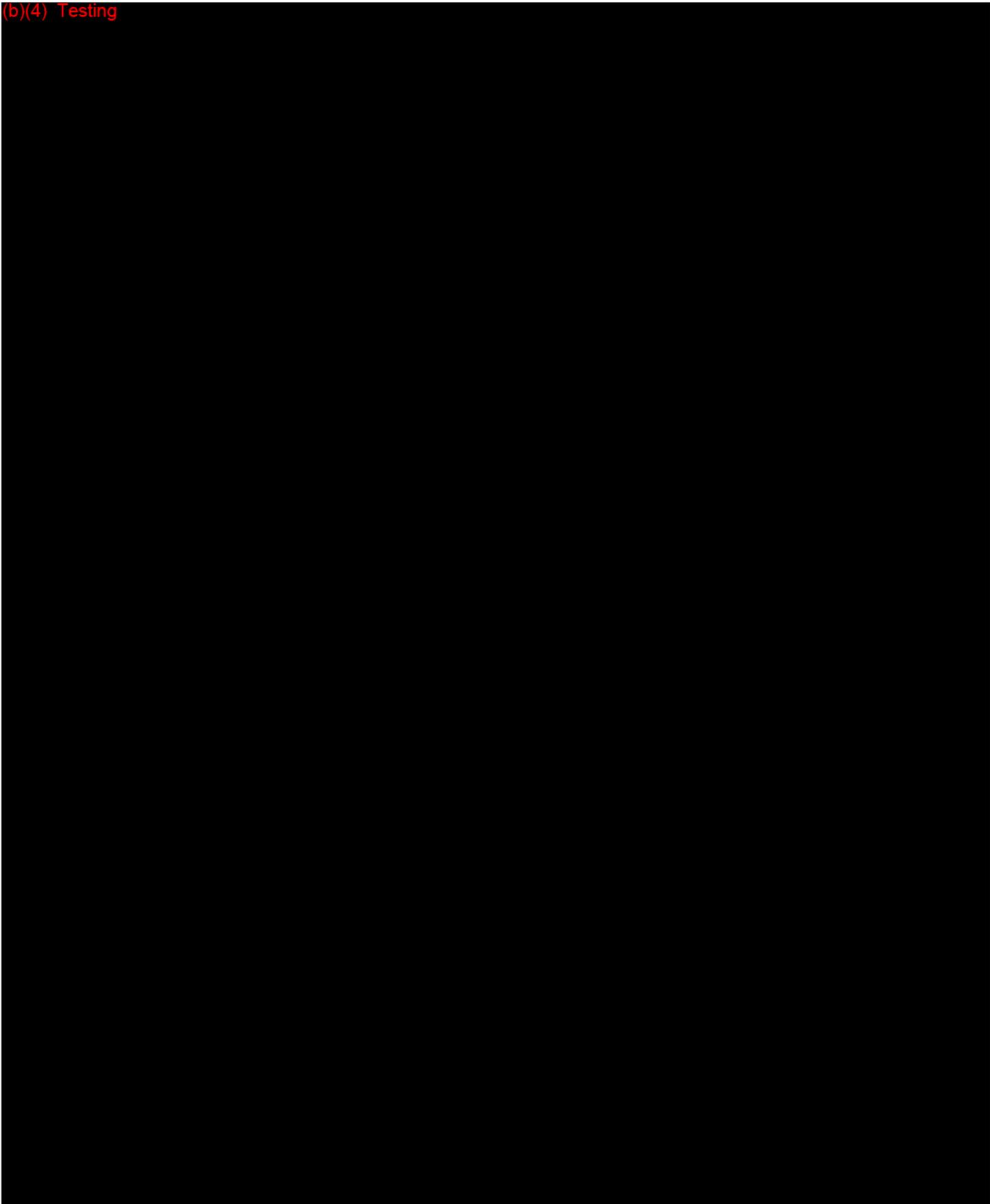


TEST RESULTS

(b)(4)



(b)(4) Testing



(b)(4)

10.13 (b)(4) TEST

PURPOSE

(b)(4)

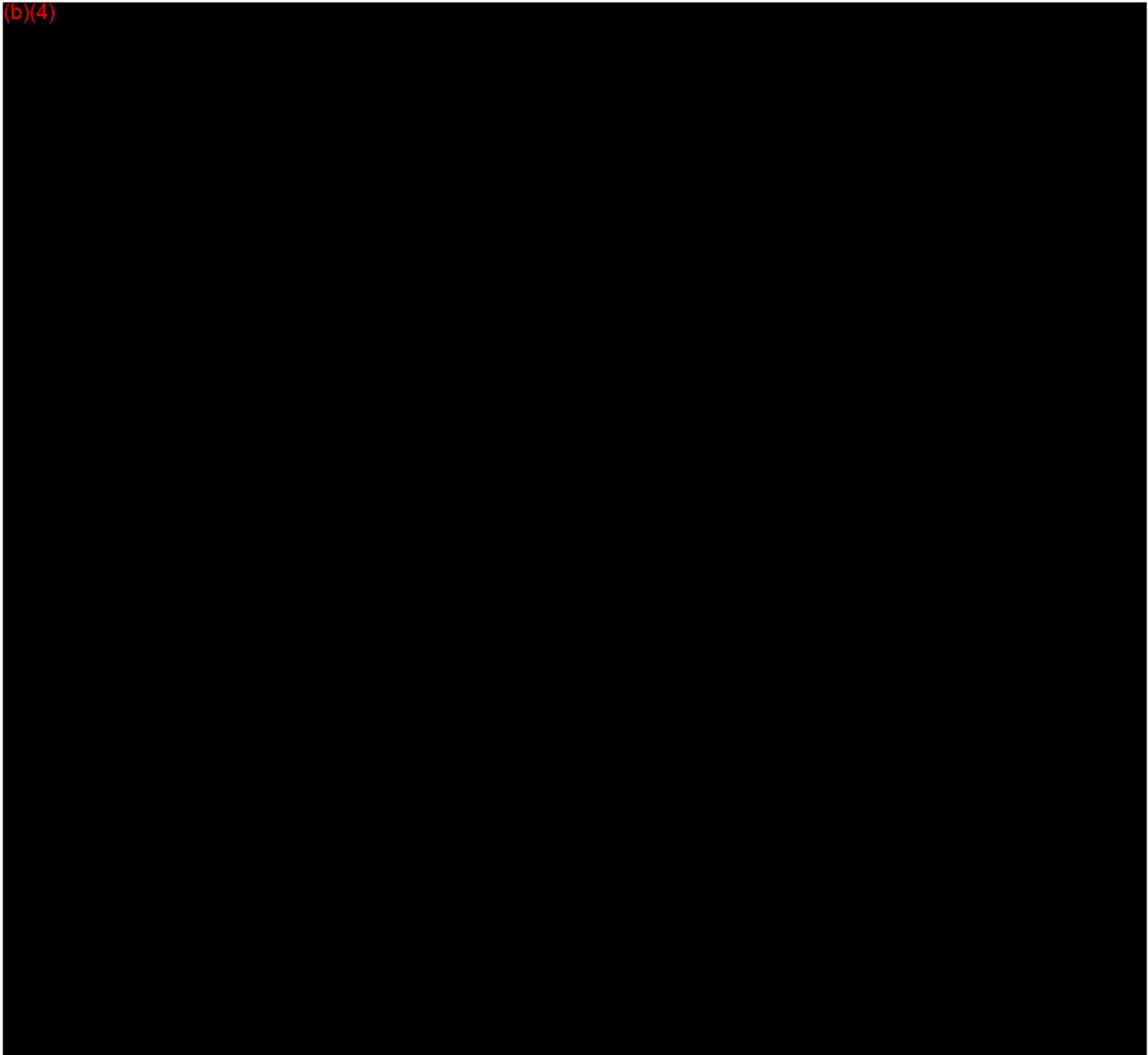
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(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)



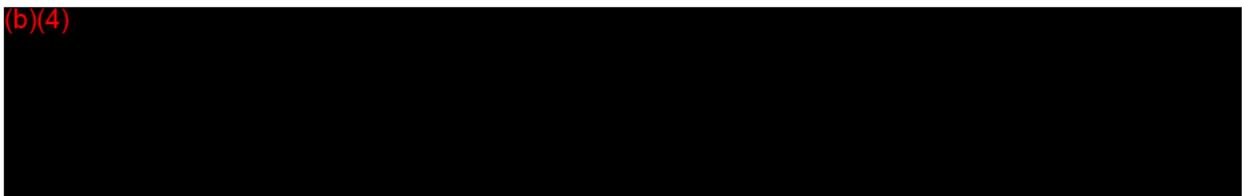
ACCEPTANCE CRITERIA

(b)(4)



TEST RESULTS

(b)(4)



(b)(4)

10.14 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.15 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)

TEST RESULTS

(b)(4)

(b)(4)

10.16 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)

10.17 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

10.18 (b)(4) TEST

PURPOSE

(b)(4)

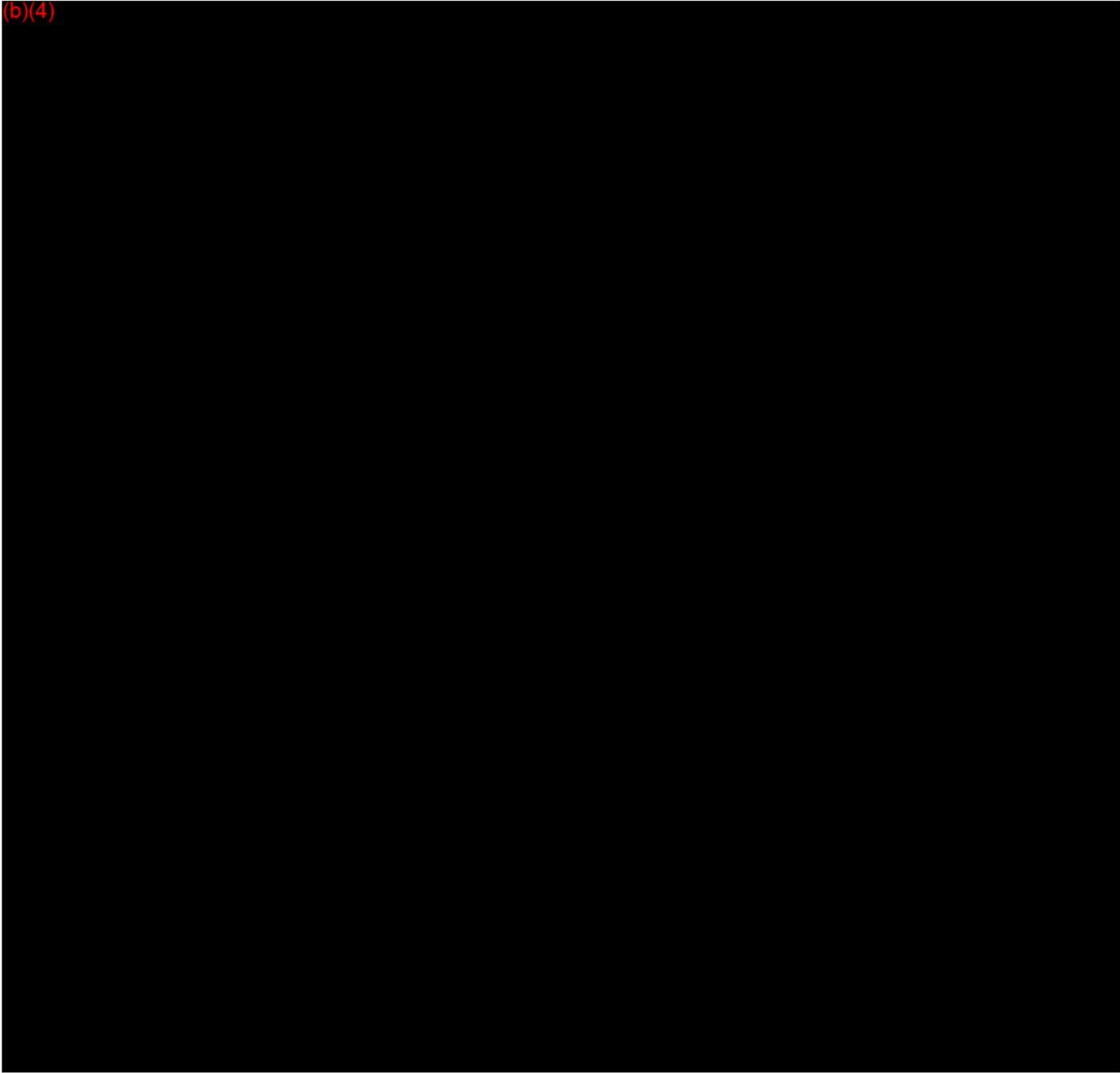
TEST REQUIREMENT

(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)



(b)(4)



(b)(4) QTR – Product Verification Test Report of (b)(4)

(b)(4)

TEST RESULTS

(b)(4)

ANALYSIS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)

10.19 (b)(4) TEST

PURPOSE

(b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4)

10.20 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

10.21 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENTS

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4) s

(b)(4)

(b)(4)

TEST RESULTS

(b)(4)

ANALYSIS

(b)(4)

(b)(4)

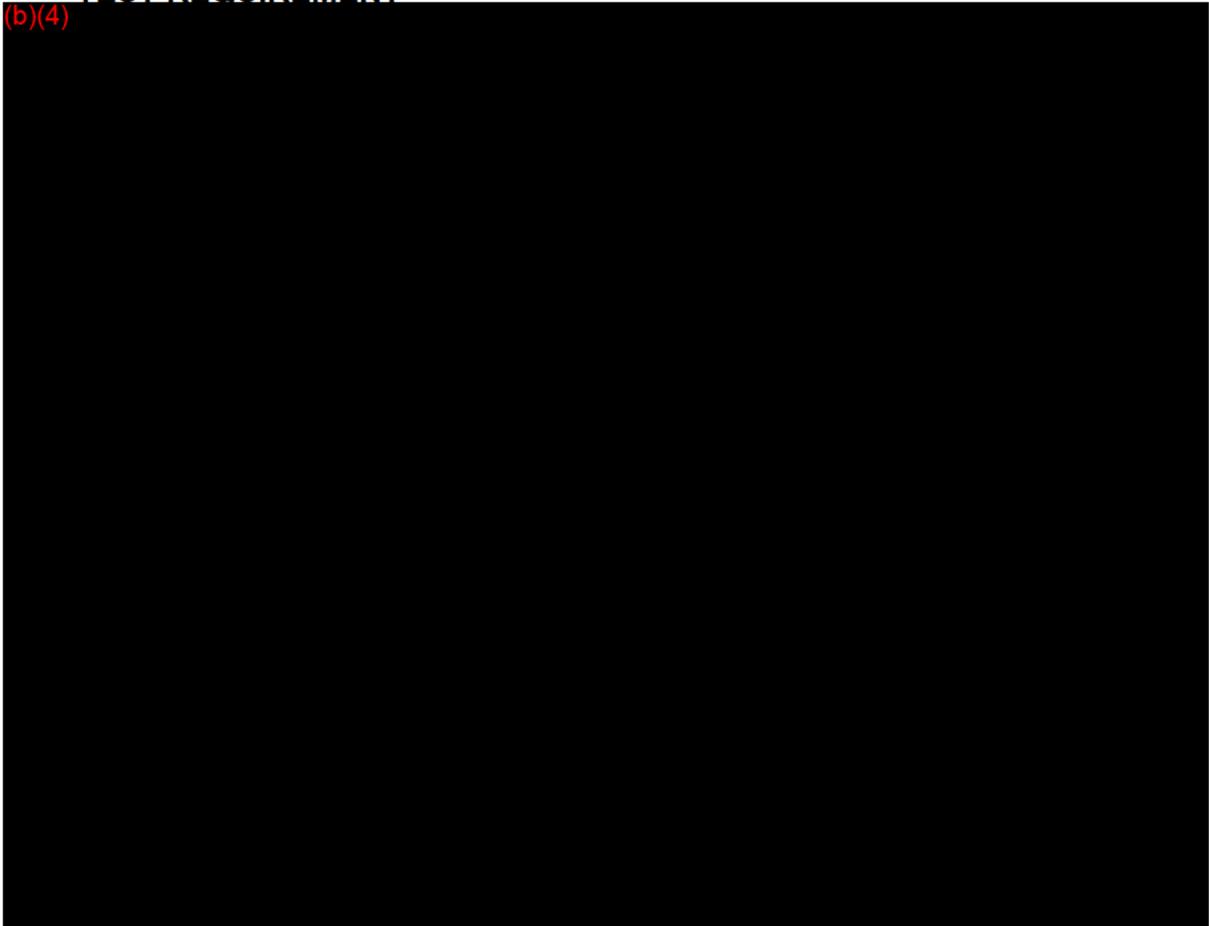
10.22 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)



ACCEPTANCE CRITERIA

(b)(4)



TEST RESULTS

(b)(4)



10.23 (b)(4) TEST

PURPOSE

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

TEST REQUIREMENT

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ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.24 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

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

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.25 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

Appendix 2

(b)(4) QTR - Product Verification Test Report of MediGuide™ Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: December 19, 2011
		Page 1(21)
Document Number: (b)(4) Testing	Revision: (b)(4)	
Document Title: QTR - Product Verification Test Report of MediGuide™ Guidewire (b)(4)		
Model numbers: DS2M032		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6)	(b)(6)	1/25/12
Design Assurance		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)	<i>Canan</i>	24 JAN 2012
Approved by/Title:		
(b)(6)	See Attached	
Regulatory Affairs (OUS)		
Approved By/Title:	(b)(6)	26 Jan 2012
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Development		
Approved By/Title:		
(b)(6)		26 Jan 2012
Program/Development Management		
Approved By/Title:		
(b)(6)		1/24/12
Design Assurance Management		

(b)(4) QTR – Product Verification Test Report of MediGuide™ Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: December 19, 2011
		Page 1(21)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report of MediGuide™ Guidewire (b)(4)		
Model numbers: DS2M032		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6)		
Design Assurance		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)		
Approved by/Title:	(b)(6)	
(b)(6)		1/18/2012
Regulatory Affairs (OUS)		
Approved By/Title:		
(b)(6)		
Development		
Approved By/Title:		
(b)(6)		
Program/Development Management		
Approved By/Title:		
(b)(6)		
Design Assurance Management		

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(b)(4) QTR – Product Verification Test Report of MediGuide™ Guidewire (b)(4)

(b)(4) Date: December 19, 2011
QTR – Product Verification Test Report of MediGuide™ Guidewire
(b)(4)
Model numbers: DS2M032

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

Table 2 Tests Included in this Test Report

Test #	Test	Requirement/ Specification
10.1	(b)(4)	(b)(4)
10.2	(b)(4)	(b)(4)
10.3	(b)(4)	(b)(4)
10.4	(b)(4)	(b)(4)
10.5	(b)(4)	(b)(4)
10.6	(b)(4)	(b)(4)
10.7	(b)(4)	(b)(4)
10.8	(b)(4)	(b)(4)
10.9	(b)(4)	(b)(4)
10.10	(b)(4)	(b)(4)

Table 3 provides rationale for certain tests that are not performed as part of this QTR and the associated rationale.

Table 3 Tests Leveraged

Test	Requirement/ Specification	Rationale
(b)(4)	(b)(4)	(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

(b)(4)

4.1 SUMMARY OF RESULTS

(b)(4)

4.2 CONCLUSIONS

(b)(4)

5.0 ASSOCIATED DOCUMENTS

Table 4 Associated Documents

	Document #	Rev #*	Document Title
5.1	(b)(4)		
5.2			
5.3			
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			
5.10			
5.11			

(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

	Document #	Rev #*	Document Title
5.12	(b)(4)		
5.13			
5.14			
5.15			
5.16			
5.17			
5.18			
5.19			

* Testing was completed with the most current revision.

(b)(4)

6.0 ASSOCIATED TEST EQUIPMENT

Table 5 Associated Test Equipment

	Description	Applicable Tests
6.1	(b)(4)	
6.2		
6.3		
6.4		
6.5		
6.6		

Where applicable, equipment was calibrated and traceable to the National Institute of Standards and Technology (NIST) prior to the initiation of tests.

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4)

(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

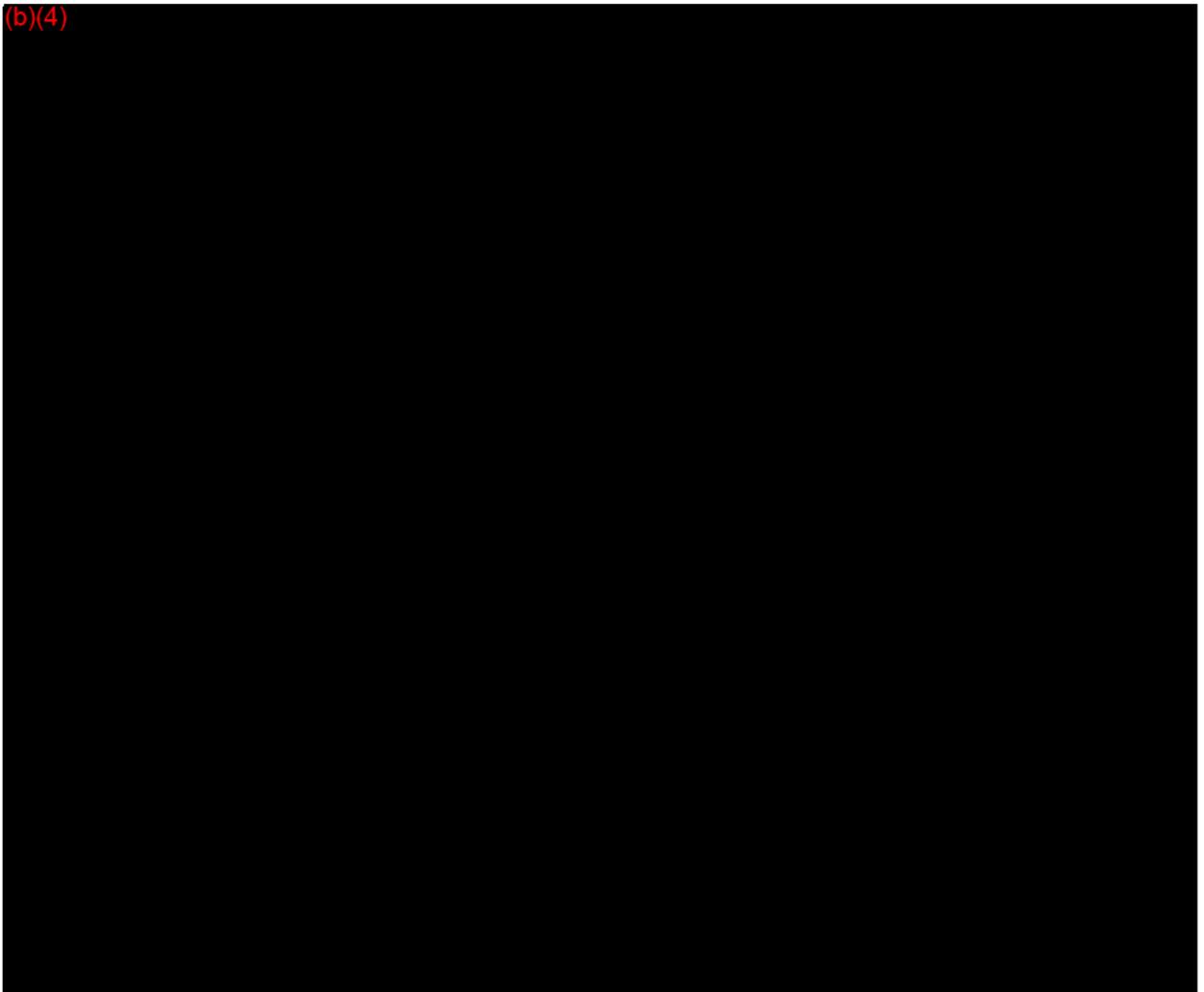
8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)



9.0 TEST SEQUENCE

(b)(4)



(b)(4)

(b)(4)

10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire (b)(4)

TEST RESULTS

(b)(4)

10.2 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.3 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4)

QTR - Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4)

(b)(4) QTR - Product Verification Test Report of MediGuide™ Guidewire (b)(4)

(b)(4)

TEST RESULTS

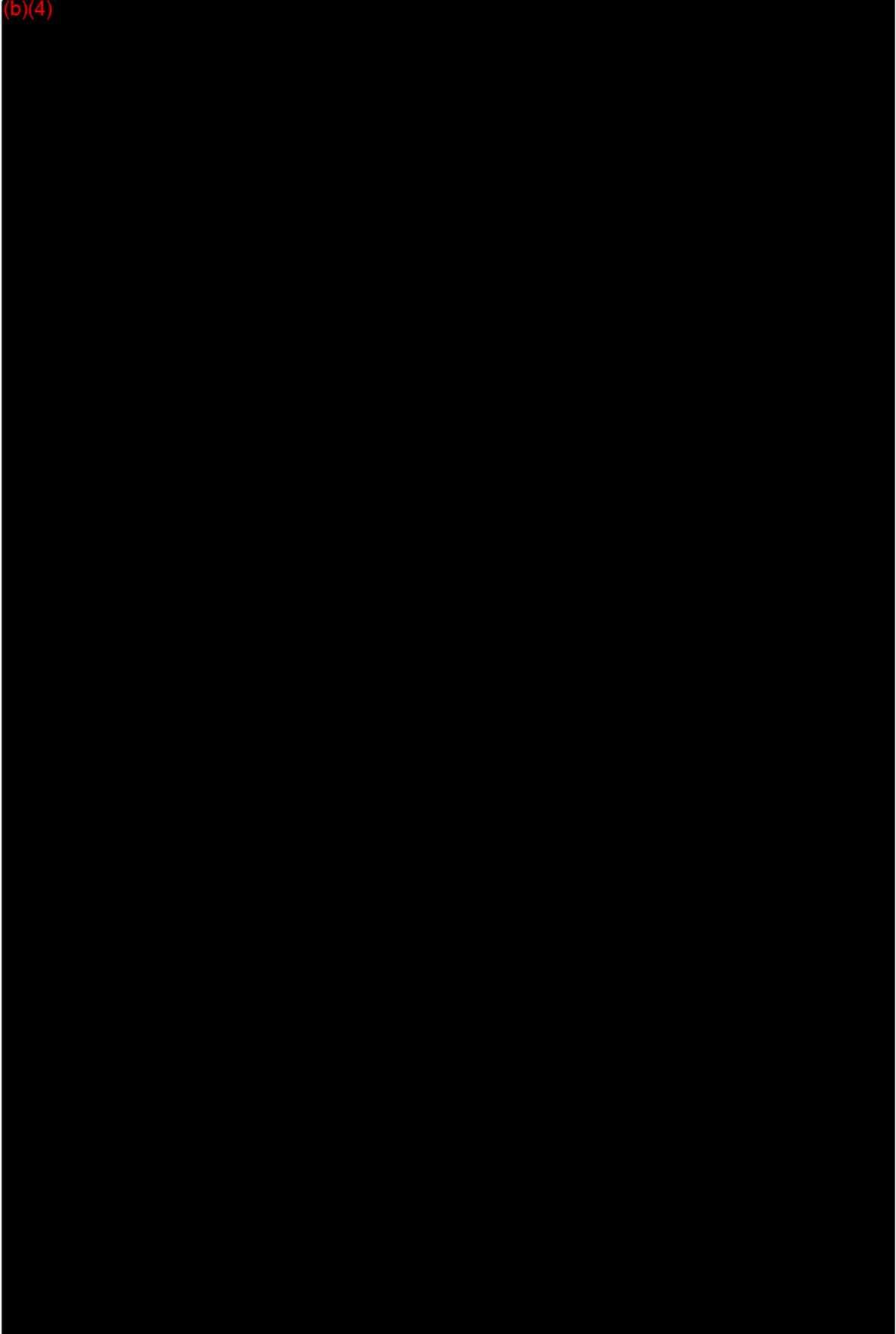
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(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

(b)(4)



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Company Confidential

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Design Assurance

(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

ANALYSIS

(b)(4)

[Redacted Analysis Content]

10.4

(b)(4)

PURPOSE

(b)(4)

[Redacted Purpose Content]

TEST REQUIREMENT

(b)(4)

[Redacted Test Requirement Content]

ACCEPTANCE CRITERIA

(b)(4)

[Redacted Acceptance Criteria Content]

TEST RESULTS

(b)(4)

[Redacted Test Results Content]

(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

(b)(4)

[Redacted content]

10.5 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.6 (b)(4)

PURPOSE

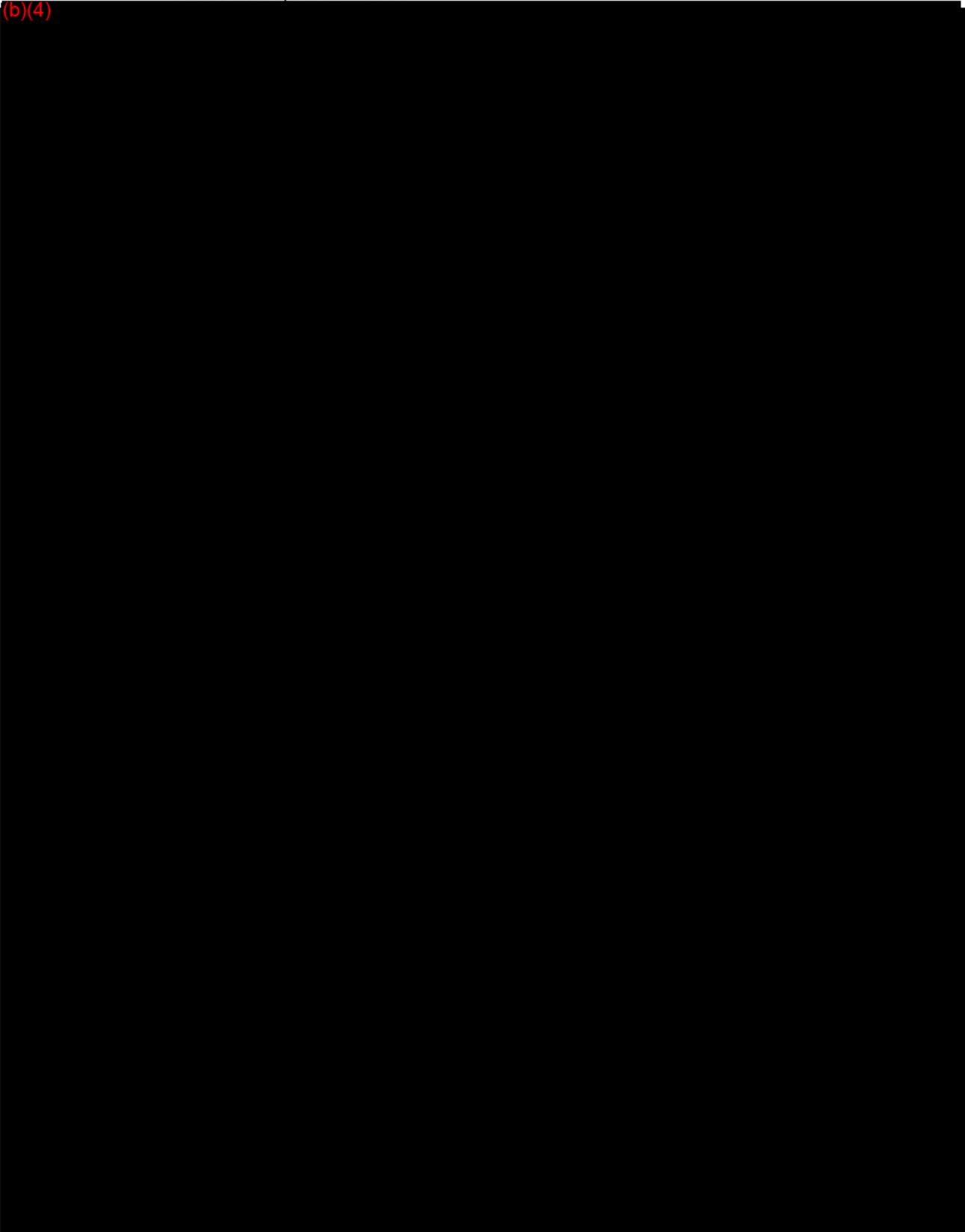
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(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire (b)(4)

TEST REQUIREMENT

(b)(4)

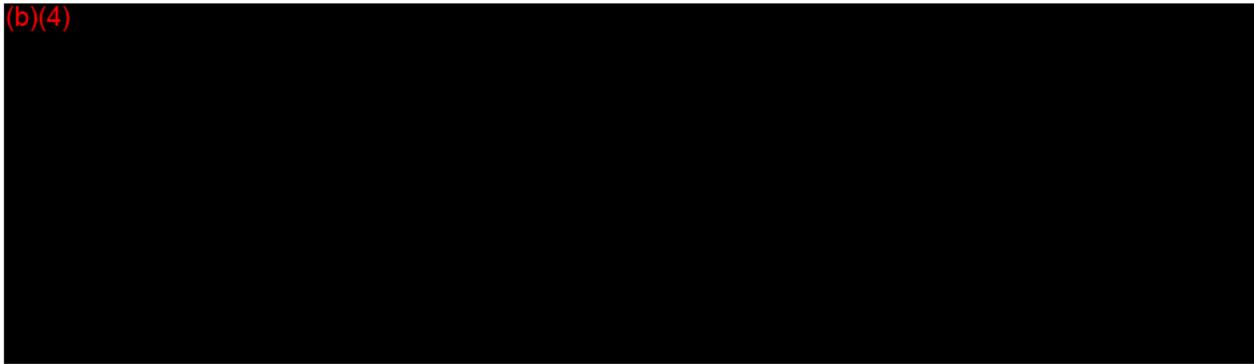


(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

(b)(4)



ACCEPTANCE CRITERIA

(b)(4)



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Design Assurance

(b)(4)

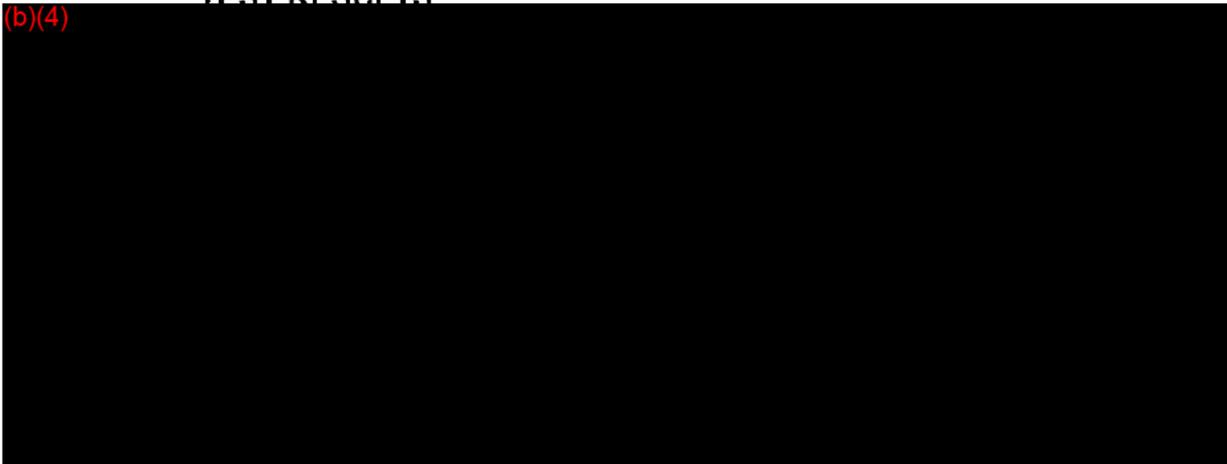
QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

* Acceptance Criteria table clarified from QT (b)(4)

TEST RESULTS

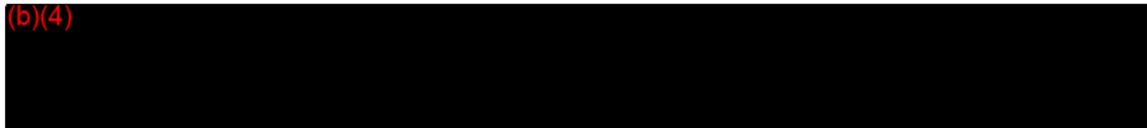
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10.7 (b)(4)(4) TEST

PURPOSE

(b)(4)



TEST REQUIREMENT

(b)(4)



(b)(4)

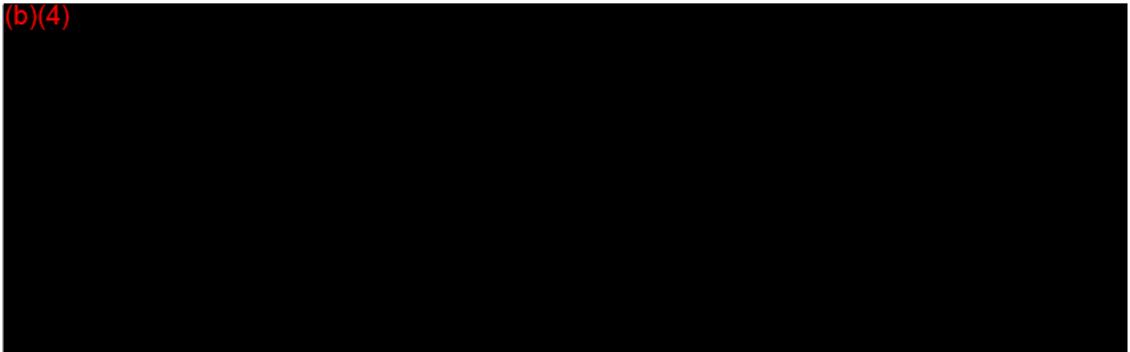
QTR – Product Verification Test Report of MediGuide™ Guidewire (b)(4)

(b)(4)



ACCEPTANCE CRITERIA

(b)(4)



(b)(4)

QTR – Product Verification Test Report of MediGuide™ Guidewire

(b)(4)

TEST RESULTS

(b)(4)

10.8

(b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4)

(b)(4)

TEST RESULTS

(b)(4)

10.9 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4)

(b)(4)

TEST RESULTS

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10.10

(b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

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(b)(4)

TEST RESULTS

(b)(4)

Appendix 3

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

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		Page 1(17)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4) (b)(4)		
Model number: DS2M030		
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Author Name/Title:	Signature:	Date:
(b)(6)	(b)(6)	1/25/12
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Approved by/Title:		
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Approved by/Title:		
(b)(6)	<i>See Attached</i>	
Regulatory Affairs (OUS)		
Approved By/Title:		
(b)(6)	<i>See Attached</i>	
Principal Development Engineer		
Approved By/Title:		
(b)(6)	<i>See Attached</i>	
Engineering Manager (Development)		
Approved By/Title:	(b)(6)	
(b)(6)		1/24/12
Manager, QA Operations		

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: December 12, 2011	
		Page 1(17)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4) (b)(4) (b)(4)			
Model number: (b)(4)			
1.0 CONCURRENCE			
Author Name/Title:	Signature:	Date:	
(b)(6) Design Assurance Engineer			
Approved by/Title:			
Colleen Canan Regulatory Affairs (US)			
Approved by/Title:	(b)(6)		
(b)(6) Regulatory Affairs (OUS)		1/19/2012	
Approved By/Title:			
(b)(6) Principal Development Engineer			
Approved By/Title:			
(b)(6) Engineering Manager (Development)			
Approved By/Title:			
(b)(6) Manager, QA Operations			

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: December 12, 2011
		Page 1(17)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)		
Model number: DS2M030		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6) Design Assurance Engineer		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)		
Approved by/Title:		
(b)(6) Regulatory Affairs (OUS)		
Approved By/Title:		
(b)(6) Principal Development Engineer	(b)(6)	26 Jan 2012
Approved By/Title:		
(b)(6) Engineering Manager (Development)	(b)(6)	26 Jan 2012
Approved By/Title:		
(b)(6) Manager, QA Operations		

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 10.2 (b)(4) Test 8
 10.3 (b)(4) (b)(4) Test 8
 10.4 (b)(4) 10
 10.5 (b)(4) Test 11
 10.6 (b)(4) Test 12
 10.7 (b)(4) Test 13
 10.8 (b)(4) Test 15
 10.9 (b)(4) Test 16
 10.10 (b)(4) 16

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(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

(b)(4) Date: December 12, 2011
QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)
(b)(4)
Model number: DS2M030

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

Table 2 Tests Included in this Test Report

Test #	Test	Requirement/ Specification
10.1	(b)(4)	(b)(4)
10.2	(b)(4)	(b)(4)
10.3	(b)(4)	(b)(4)
10.4	(b)(4)	(b)(4)
10.5	(b)(4)	(b)(4)
10.6	(b)(4)	(b)(4)
10.7	(b)(4)	(b)(4)
10.8	(b)(4)	(b)(4)
10.9	(b)(4)	(b)(4)
10.10	(b)(4)	(b)(4)

(b)(4)

4.1 SUMMARY OF RESULTS

(b)(4)

4.2 CONCLUSIONS

(b)(4)

5.0 ASSOCIATED DOCUMENTS

Table 3 Associated Documents

	Document #	Rev #*	Document Title
5.1	(b)(4)		

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

	Document #	Rev #*	Document Title
5.2	(b)(4)		
5.3			
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			
5.10			
5.11			
5.12			
5.13			
5.14			

(b)(4)

6.0 ASSOCIATED TEST EQUIPMENT

Table 4 Associated Test Equipment

	Description	Applicable Tests
6.1	(b)(4)	
6.2		
6.3		
6.4		

Where applicable, equipment was calibrated and traceable to the National Institute of Standards and Technology (NIST) prior to the initiation of tests.

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire

(b)(4)

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4)

[Redacted content for section 7.0]

8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)

[Redacted content for section 8.0]

9.0 TEST SEQUENCE

(b)(4)

[Redacted content for section 9.0]

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire

(b)(4)

10.0 TEST PROCEDURE

10.1

(b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire

(b)(4)

TEST RESULTS

(b)(4)

10.2 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.3 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

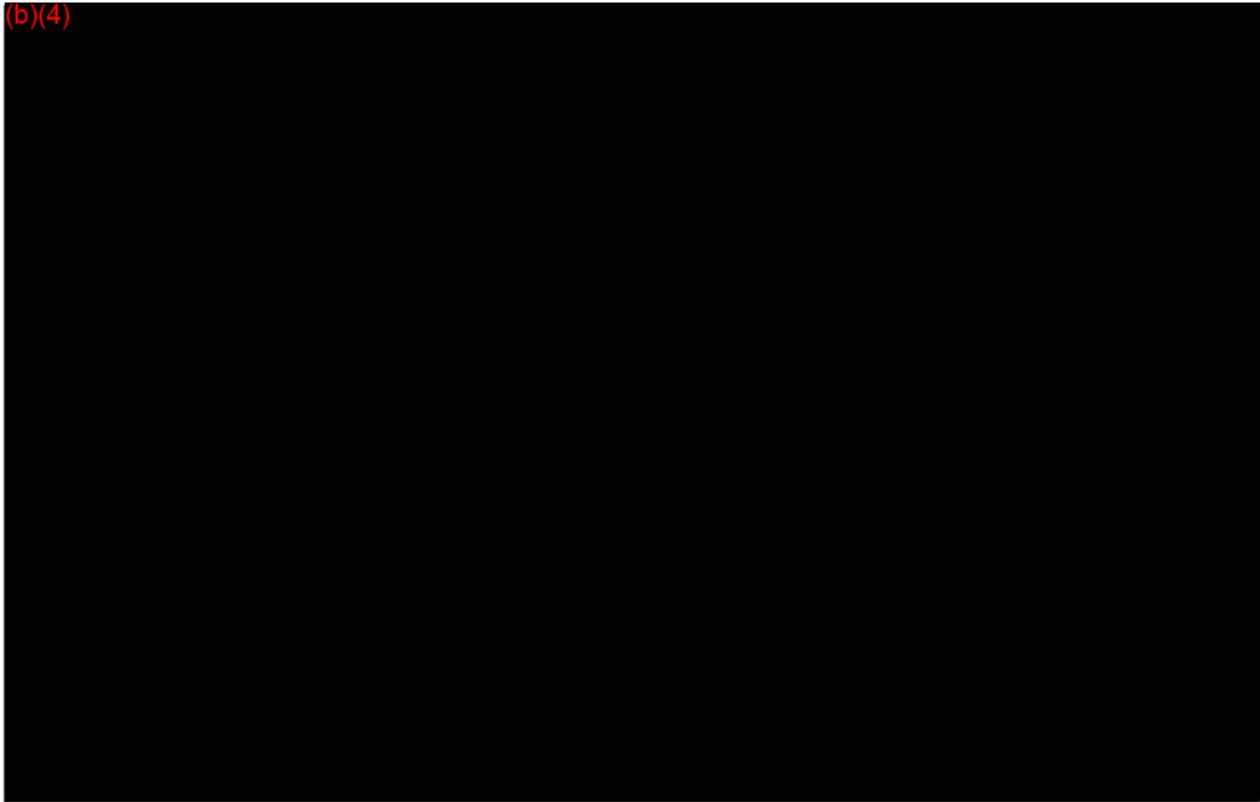
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(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire

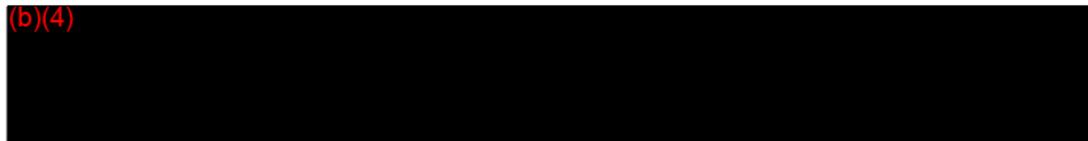
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(b)(4)



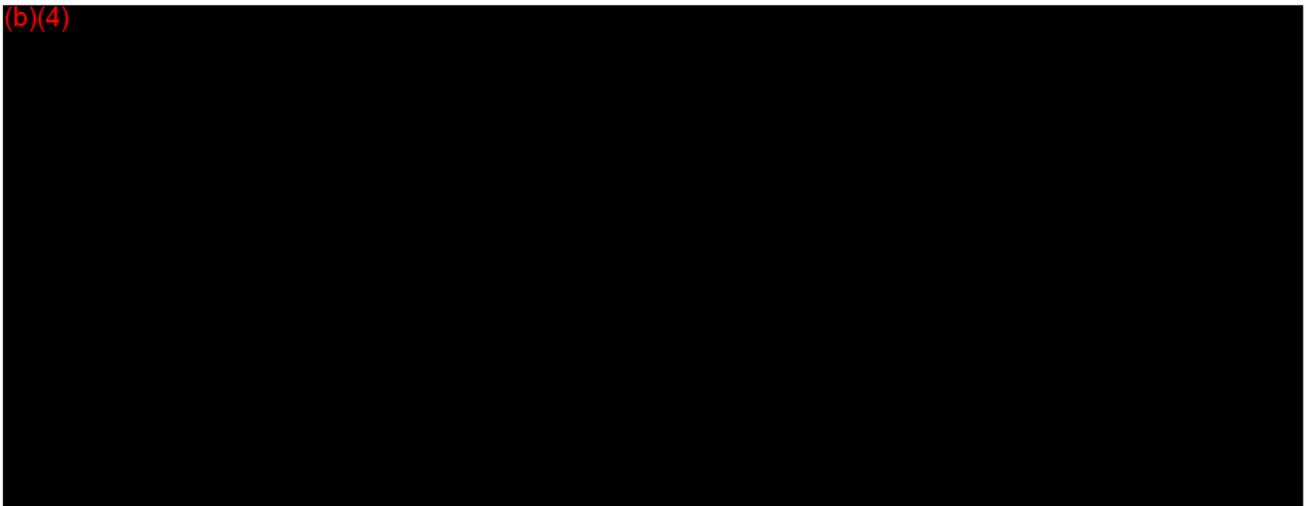
ACCEPTANCE CRITERIA

(b)(4)



TEST RESULTS

(b)(4)



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9(17)

Design Assurance

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire

(b)(4)

10.4

(b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4)

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b) (4)

TEST RESULTS

(b)(4)

10.5 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

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

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire

(b)(4)

(b)(4)

TEST RESULTS

(b)(4)

10.6

(b)(4)

TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)



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MEDICAL CONTROL SYSTEMS

Company Confidential

12(17)

Design Assurance

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.7 (b)(4) TEST

PURPOSE

(b)(4)

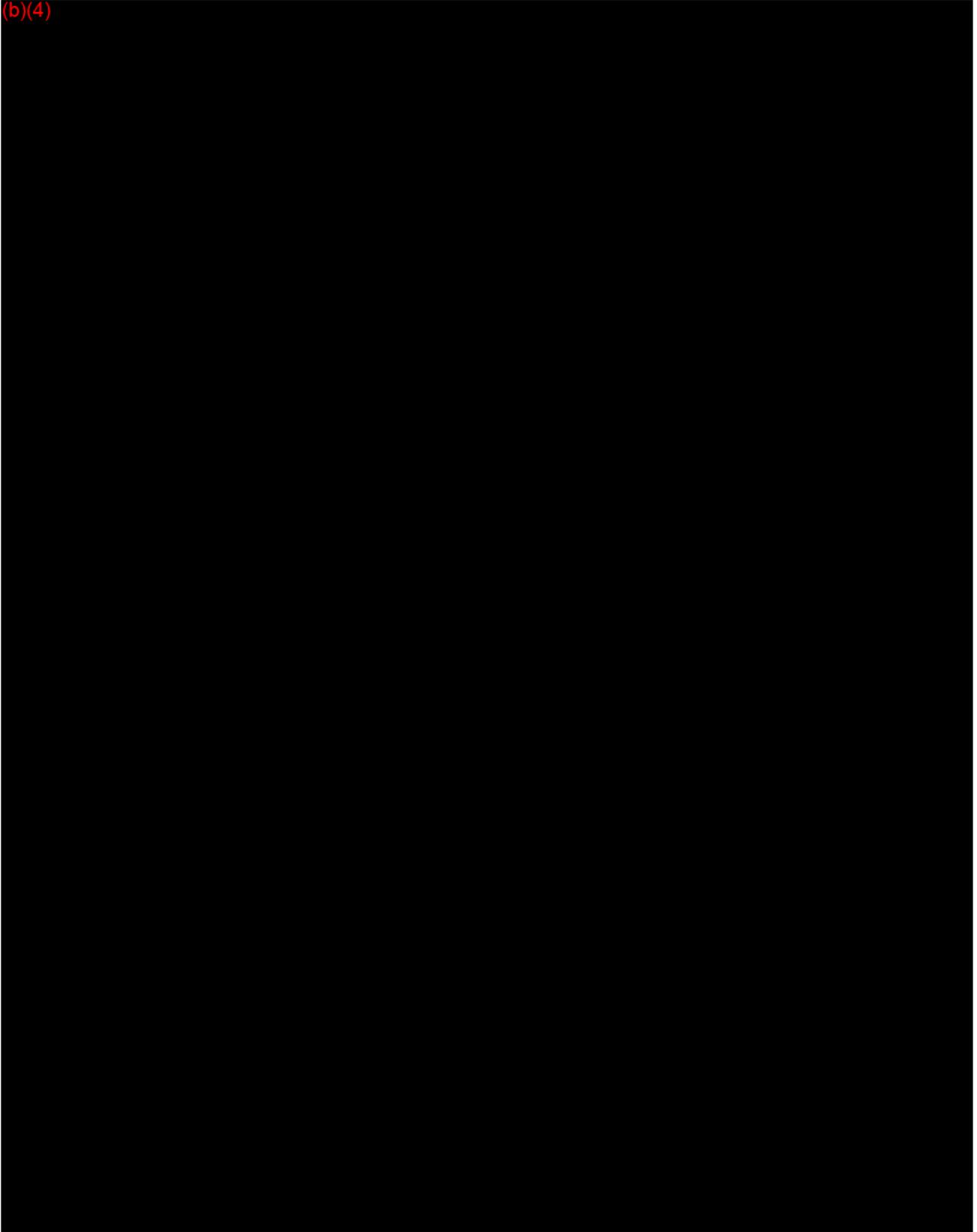
TEST REQUIREMENT

(b)(4)

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

(b)(4)



Company Confidential

14(17)

Design Assurance

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

[Redacted content]

TEST RESULTS

(b)(4)

[Redacted content]

10.8 (b)(4) TEST

PURPOSE

(b)(4)

[Redacted content]

TEST REQUIREMENT

(b)(4)

[Redacted content]

(b)(4) QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.9 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.10 (b)(4)

PURPOSE

(b)(4)

(b)(4)

QTR – Product Verification Test Report for MediGuide™ Guidewire (b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

Appendix 4

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: December 12, 2011
		Page 1(31)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report of MediGuide™ (b)(4) Model number: DS2M031		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6)	(b)(6)	1/26/12
Design Assurance		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)	<i>Canan</i>	24-JAN-2012
Approved by/Title:		
(b)(6)	See Attached	
Regulatory Affairs (OUS)		
Approved By/Title:		
(b)(6)	See Attached	
Development		
Approved By/Title:		
(b)(6)	See Attached	
Program Management		
Approved By/Title:	(b)(6)	
(b)(6)		1/24/12
Design Assurance Management		

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: December 12, 2011	
		Page 1(31)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR – Product Verification Test Report of MediGuide™ (b)(4) Model number: DS2M031			
1.0 CONCURRENCE			
Author Name/Title:	Signature:	Date:	
(b)(6) Design Assurance			
Approved by/Title:			
Colleen Canan Regulatory Affairs (US)			
Approved by/Title:	(b)(6)	1/26/12	
(b)(6) Regulatory Affairs (OUS)			
Approved By/Title:			
(b)(6) Development			
Approved By/Title:			
(b)(6) Program Management			
Approved By/Title:			
(b)(6) Design Assurance Management			

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: December 12, 2011
		Page 1(31)
Document Number (b)(4)	Revision (b)(4)	
Document Title: QTR – Product Verification Test Report of MediGuide™ (b)(4) Model number: DS2M031		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6) Design Assurance		
Approved by/Title:		
(b)(6) Regulatory Affairs (US)		
Approved by/Title:		
(b)(6) Regulatory Affairs (OUS)		
Approved By/Title:	(b)(6)	
(b)(6) Development	(b)(6)	24 Jan 2012
Approved By/Title:	(b)(6)	
(b)(6) Program Management	(b)(6)	24 Jan 2012
Approved By/Title:		
(b)(6) Design Assurance Management		

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(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

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Figure 10 (b)(4) Test Set-up 29

(b)(4) [REDACTED] QTR – Product Verification Test Report of MediGuide™ (b)(4) [REDACTED]

(b)(4) [REDACTED] Date: December 12, 2011
QTR – Product Verification Test Report of MediGuide™ (b)(4) [REDACTED]
Model number: DS2M031

3.0 PURPOSE

(b)(4) [REDACTED]

4.0 SCOPE

(b)(4) [REDACTED]

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

Table 2 references the tests included in this test plan.

Table 2 Tests Included in this Test Plan

Test #	Test	Requirement/ Specification
10.1	(b)(4)	(b)(4)
10.2	(b)(4)	(b)(4)
10.3	(b)(4)	(b)(4)
10.4	(b)(4)	(b)(4)
10.5	(b)(4)	(b)(4)
10.6	(b)(4)	(b)(4)
10.7	(b)(4)	(b)(4)
10.8	(b)(4)	(b)(4)
10.9	(b)(4)	(b)(4)
10.10	(b)(4)	(b)(4)
10.11	(b)(4)	(b)(4)
10.12	(b)(4)	(b)(4)
10.13	(b)(4)	(b)(4)
10.14	(b)(4)	(b)(4)
10.15	(b)(4)	(b)(4)

The packaging materials (pouch/box), label stock and printing ink and process used to package the MediGuide Extension cable are identical to those used in the CPS Aim SL Catheter packaging. Labeling testing performed on CPS Aim SL Catheters through (b)(4) is representative of labeling testing for MediGuide

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(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

4.1 SUMMARY OF RESULTS

(b)(4)

4.2 CONCLUSIONS

(b)(4)

5.0 ASSOCIATED DOCUMENTS

Table 3 Associated Documents

	Document #	Rev #*	Document Title
5.1	(b)(4)		
5.2			
5.3			
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			

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(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

	Document #	Rev #*	Document Title
5.10	(b)(4)		
5.11			
5.12			
5.13			
5.14			
5.15			
5.16			
5.17			
5.18			
5.19			

(b)(4)

6.0 ASSOCIATED TEST EQUIPMENT

Table 4 Associated Test Equipment

	Description	Applicable Tests
6.1	(b)(4)	
6.2		
6.3		
6.4		
6.5		
6.6		
6.7		
6.8		

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4)

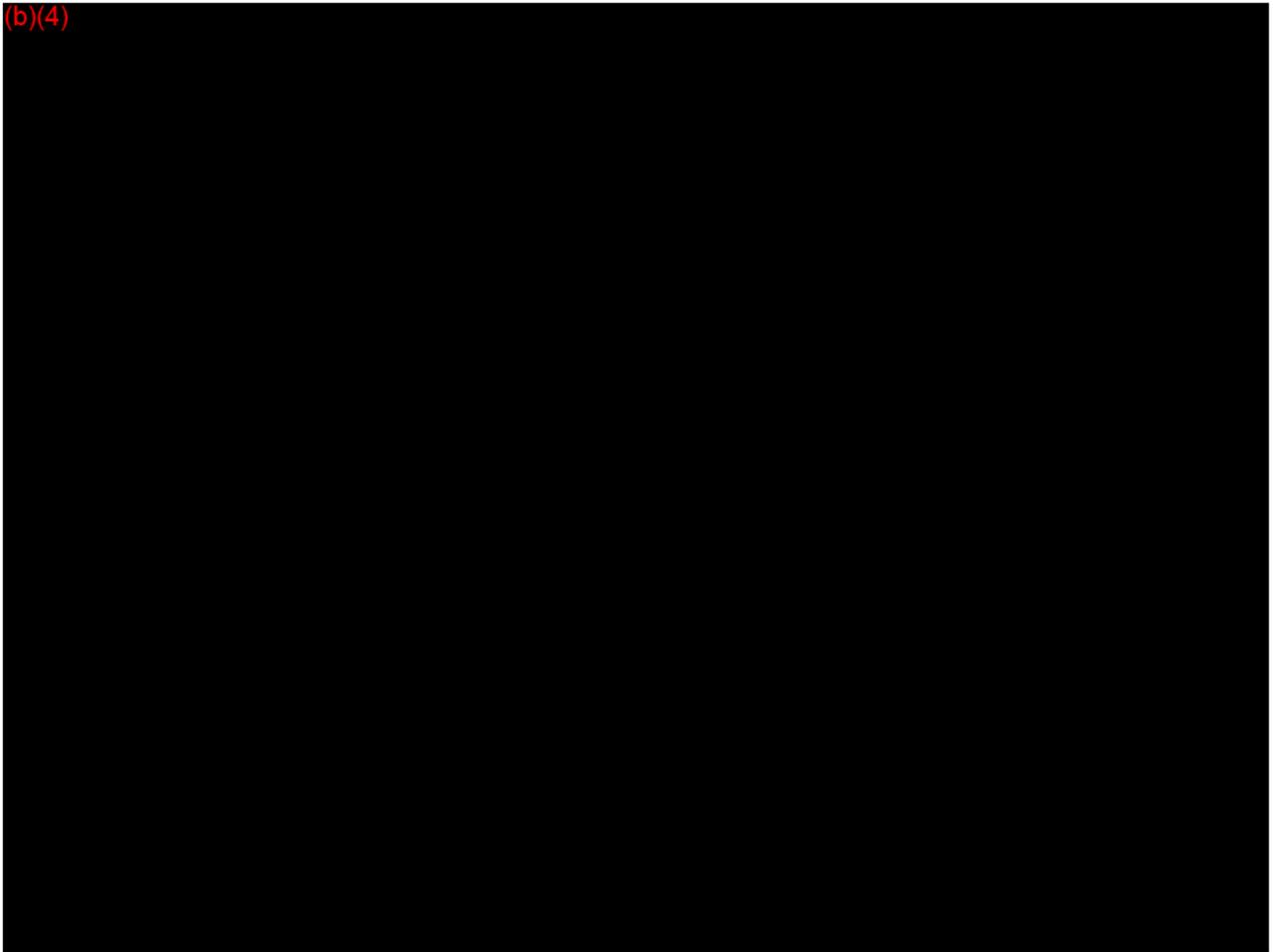
8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

9.0 TEST SEQUENCE

(b)(4)



(b)(4)

QTR – Product Verification Test Report of MediGuide™

(b)(4)

FUNCTIONAL TEST FLOW

(b)(4)



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(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

TEST RESULTS

(b)(4)

10.2 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

ANALYSIS

(b)(4)

10.3 (b)(4) TEST

PURPOSE

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

10.4 (b)(4) STERILIZATION

(b)(4)

10.5 (b)(4) STERILIZATION

(b)(4)

10.6 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

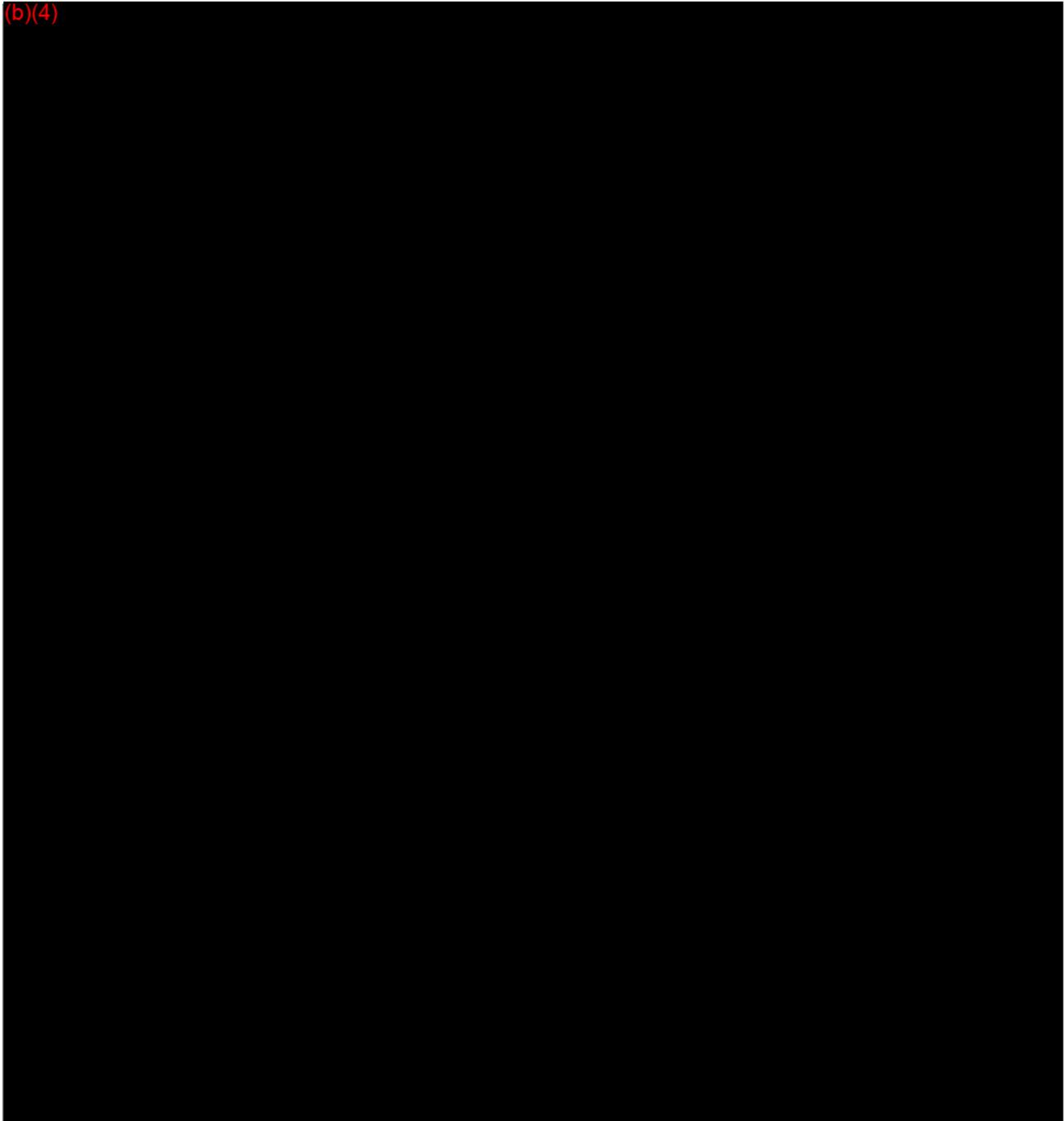
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ACCEPTANCE CRITERIA

(b)(4)

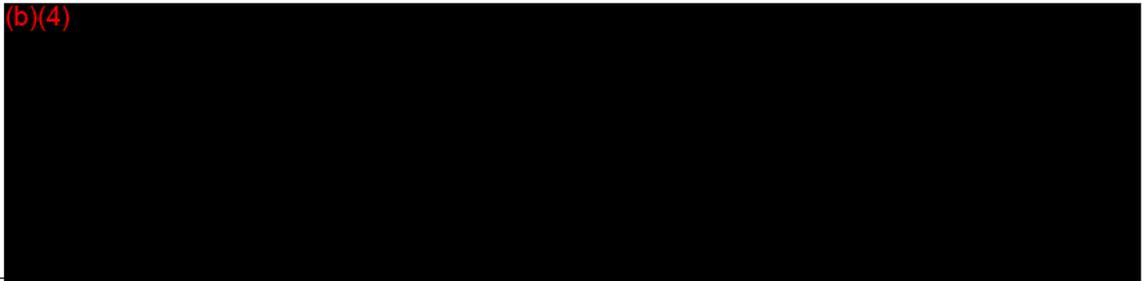
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(b)(4)



TEST RESULTS

(b)(4)



(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

ANALYSIS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

1

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

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

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

10.8 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.9 (b) (4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.10 (b)(4)

PURPOSE

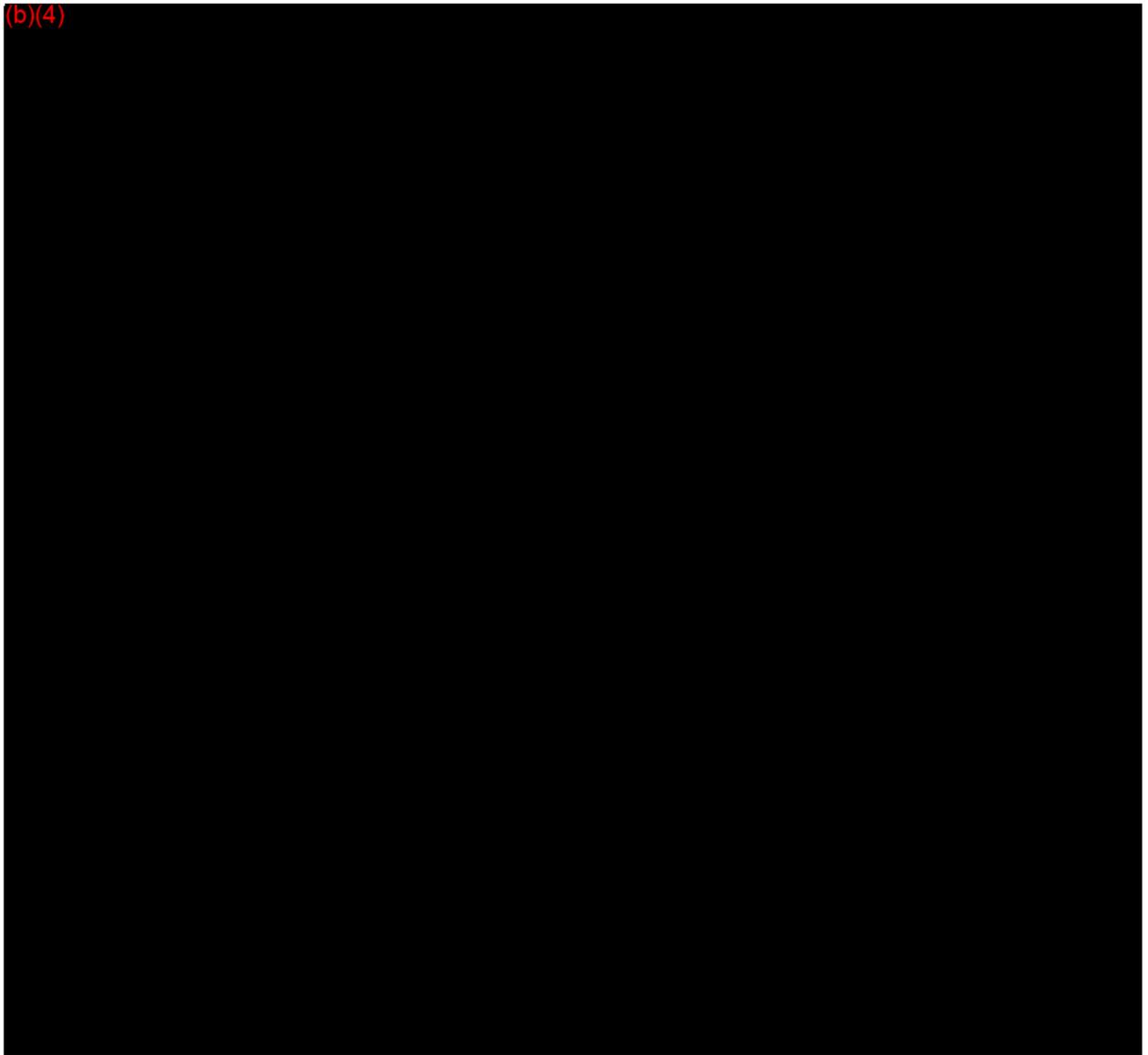
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TEST REQUIREMENT

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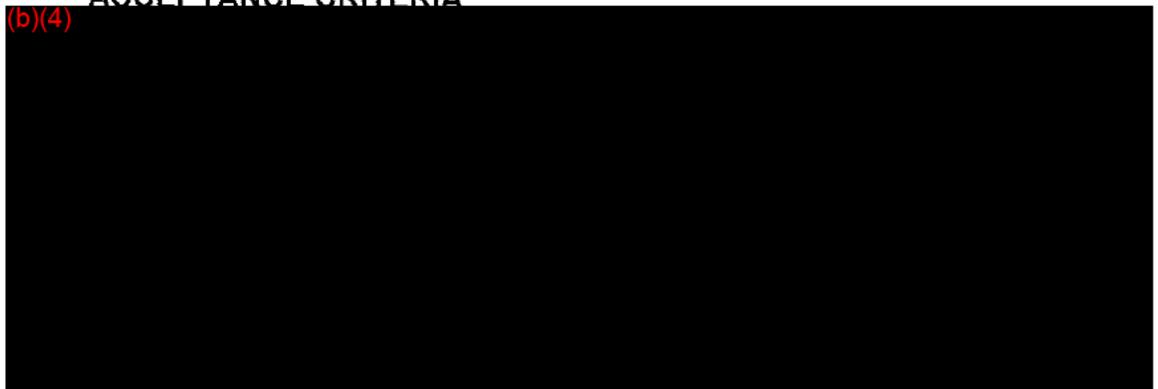
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(b)(4)



ACCEPTANCE CRITERIA

(b)(4)



(b)(4) QTR – Product Verification Test Report of MediGuide (b)(4)

(b)(4)

TEST RESULTS

(b)(4)

ANALYSIS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

10.11 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

10.12 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

10.13 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR – Product Verification Test Report of MediGuide™ (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR - Product Verification Test Report of MediGuide (b)(4)

10.14 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4)

QTR – Product Verification Test Report of MediGuide™

(b)(4)

(b)(4)

10.15

(b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

Appendix 5



Document name
Sterilization Validation Guidewire (b)(4)

Document Id
(b)(4)

Date
2011-09-06

Author
2011-09-06 (b)(6) **Manager**
Microbiology & Sterilization
Name/Function

Reviewed
2011-09-07 (b)(6) (b)(6)
PPO
Name/Function

Reviewed
2011-09-07 (b)(6) (b)(6) / **QE**
Name/Function

Reviewed
2011-09-07 (b)(6) (b)(6) (b)(6) / **Process Engineer – Microbiology and Sterilization CRM**
Name/Function

Reviewed
2011-09-07 (b)(6) (b)(6)
Name/Function



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Document name

(b)(4) Sterilization Validation
Guidewire

Document Id

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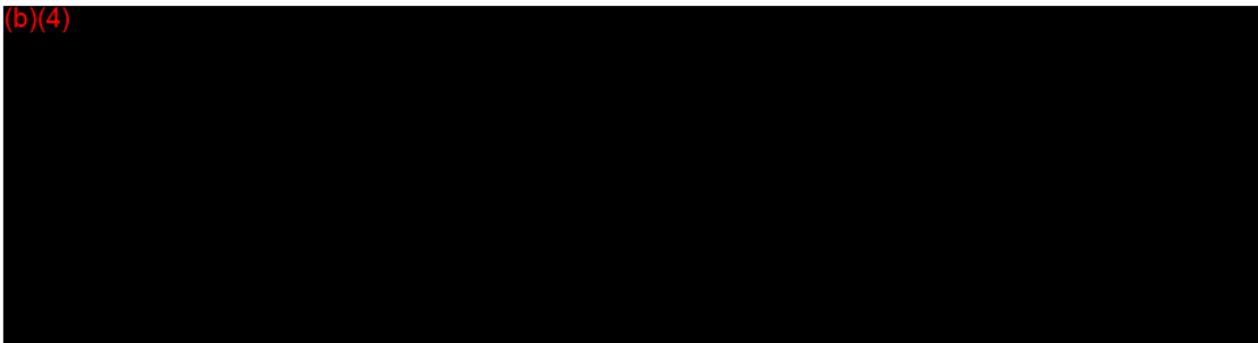
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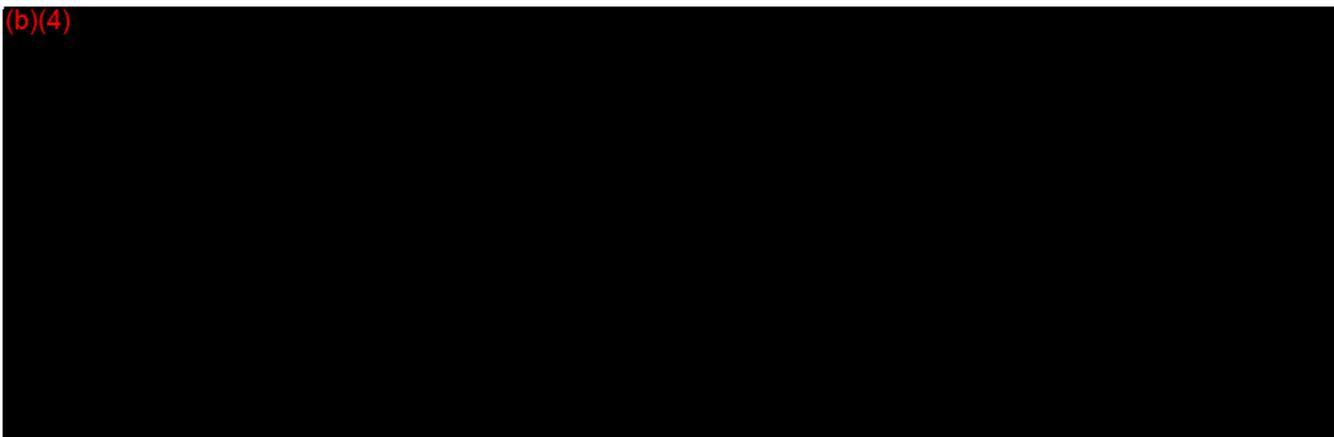
1 INTRODUCTION

(b)(4)



2 SCOPE

(b)(4)





ST. JUDE MEDICAL

Document name

Document Id

(b)(4) **Sterilization Validation
Guidewire**

(b)(4)

(b)(4)

3 ACCEPTANCE CRITERIA

(b)(4)

4 APPLIED STANDARDS

(b)(4)



ST. JUDE MEDICAL

Document name

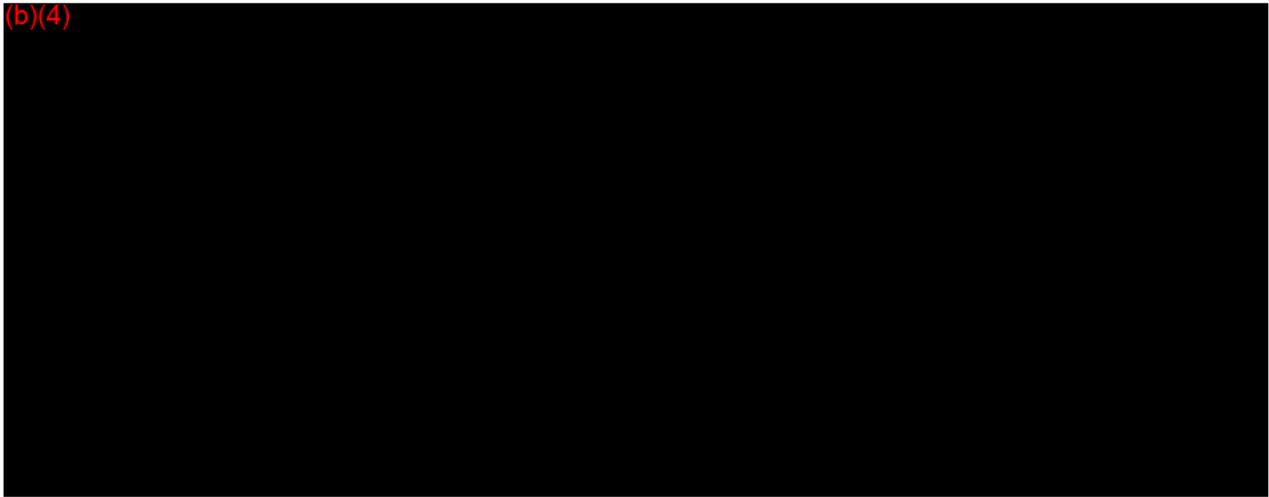
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Guidewire

Document Id

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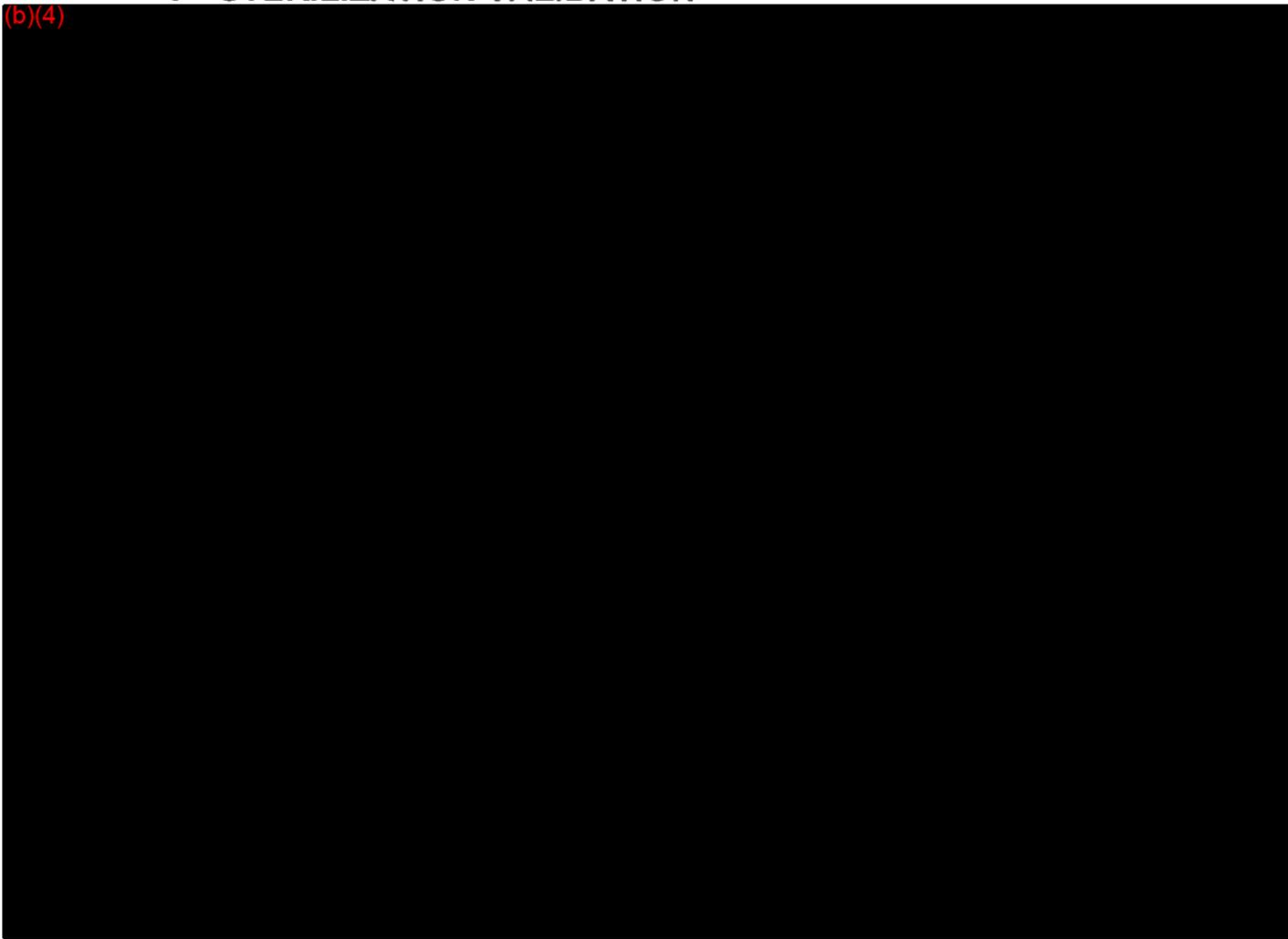
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6 STERILIZATION VALIDATION

(b)(4)





ST. JUDE MEDICAL

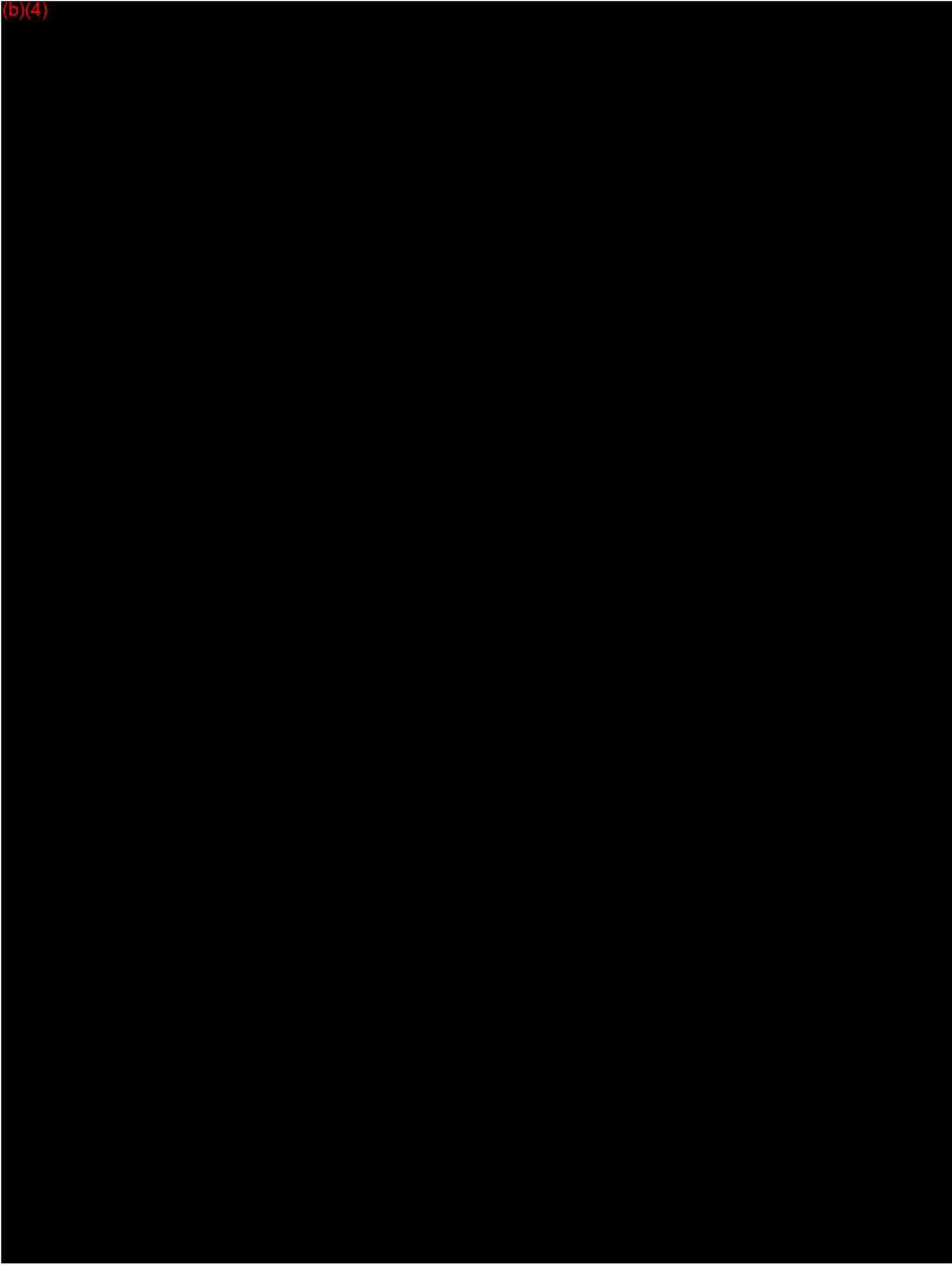
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Guidewire**

Document Id

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ST. JUDE MEDICAL

Document name

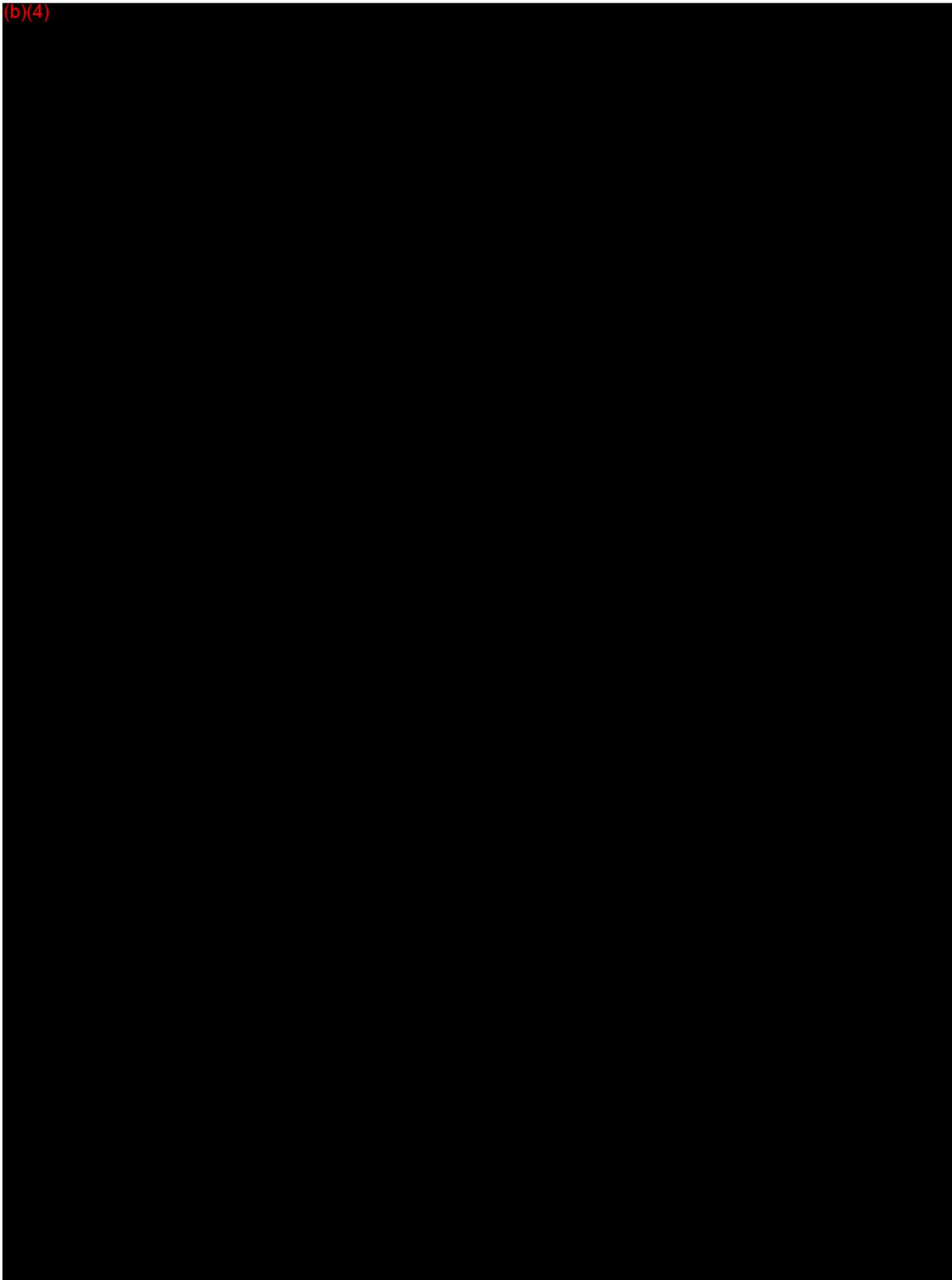
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Guidewire**

Document Id

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(b)(4)





ST. JUDE MEDICAL

Document name

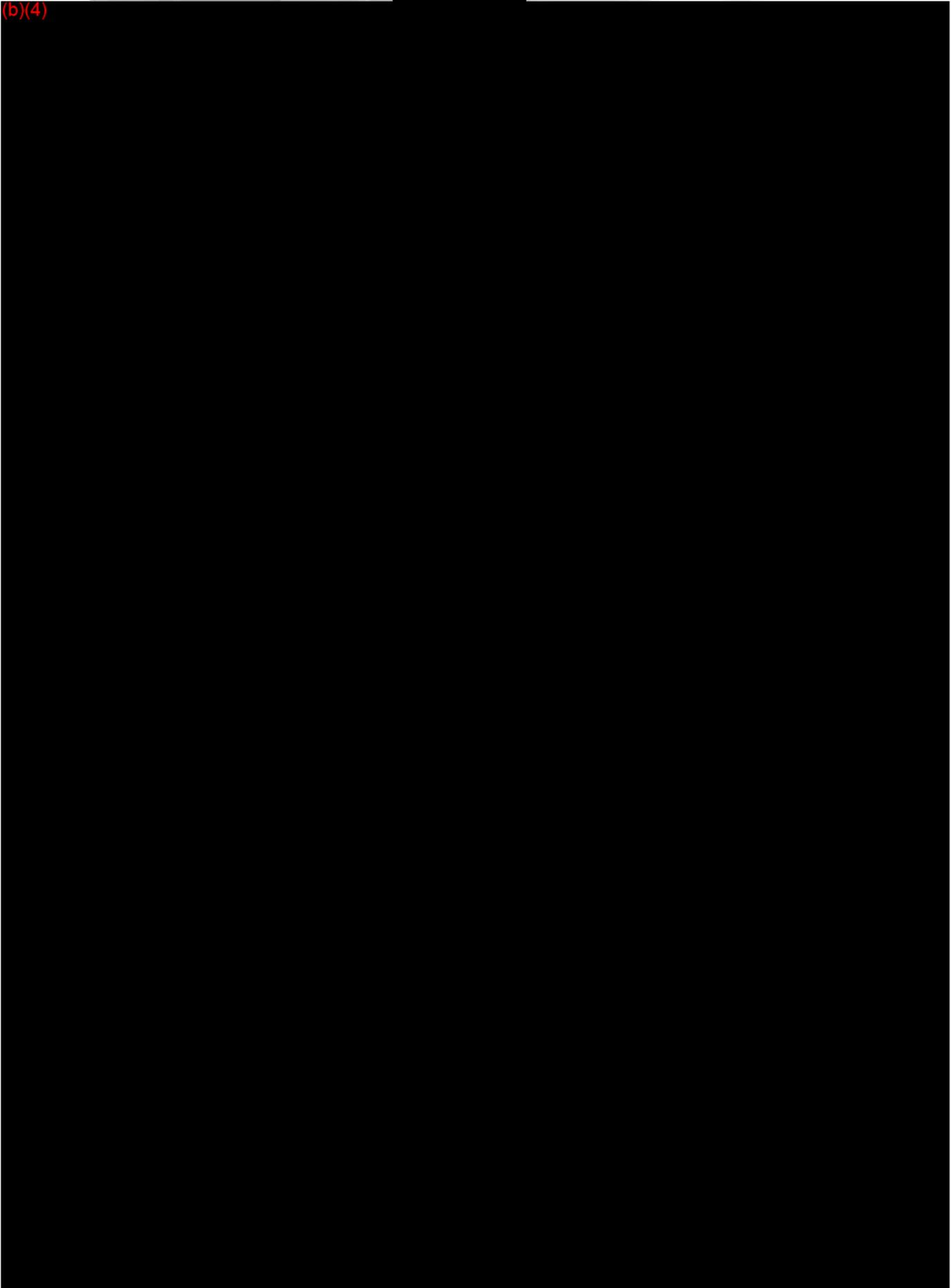
Document Id

**Sterilization Validation
Guidewire**

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(b)(4)





ST. JUDE MEDICAL

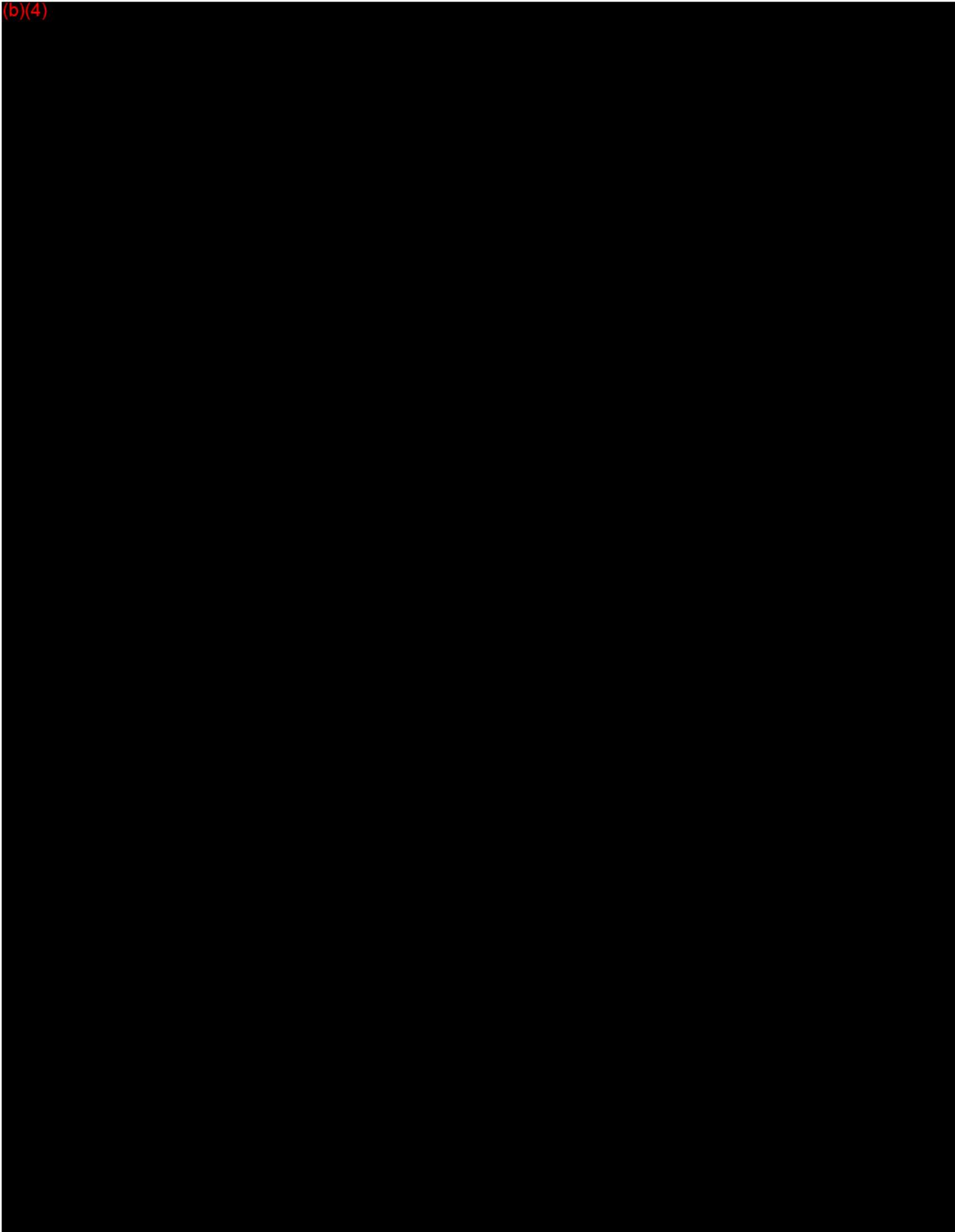
Document name

Document Id

(b)(4) **Sterilization Validation
Guidewire**

(b)(4)

(b)(4)





ST. JUDE MEDICAL

Document name

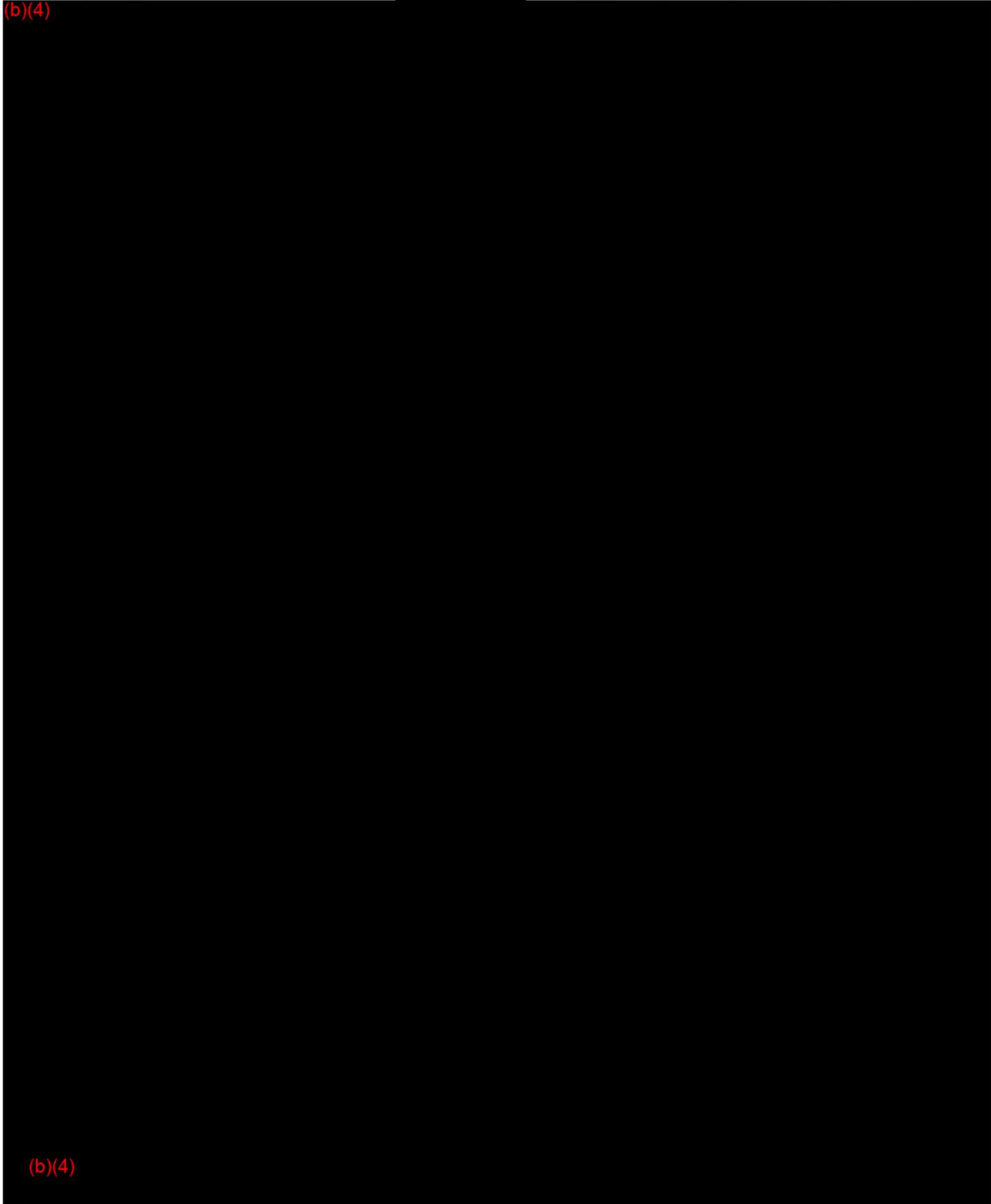
**Sterilization Validation
Guidewire**

Document Id

(b)(4)

(b)(4)

(b)(4)



(b)(4)



ST. JUDE MEDICAL

Document name

Sterilization Validation
Guidewire

Document Id

(b)(4)

(b)(4)



(b)(4)



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Document name

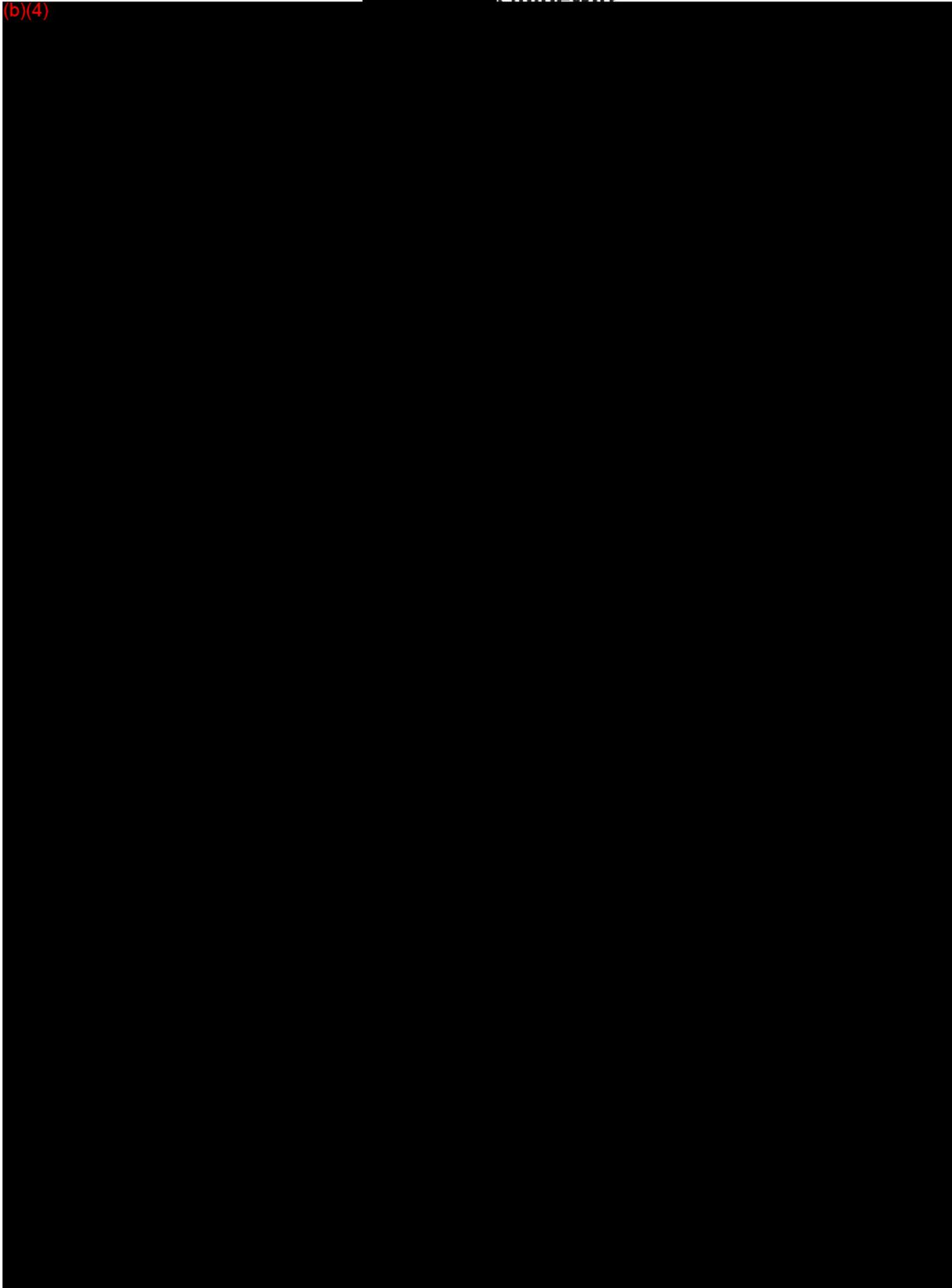
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Guidewire

Document Id

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(b)(4)

(b)(4)





ST. JUDE MEDICAL

Document name

(b)(4) Sterilization Validation
(b)(4) Guidewire

Document id

(b)(4)

8 Attachments

1. Sterilization documentation, sterilization numbers (b)(4) and (b)(4)
2. Process parameters of cycle (b)(4)
3. (b)(4) certificate
4. (b)(4)
5. (b)(4)
6. Sterilization efficiency

Appendix 6

 <p>ST. JUDE MEDICAL MORE CONTROL. LESS RISK.</p>	<p>No. (b)(4) Division: Atrial Fibrillation Document Type: Sterilization Validation Version: (b) Page: 1 of 6</p>
<p>Sterilization Qualification Report of the MediGuide (b)(4) into Cycle</p>	
<p>Report: (b)(4) Version (b)</p>	
<p>Protocol Number: (b)(4)</p>	
<p>Version History</p> <p>New document (b)</p>	

Version history and electronic signatures are contained in Windchill



(b)(4) Version (b)(4)
Sterilization Validation
3 of 6

Sterilization Qualification Report of the MediGuide (b)(4)

(b)(4)

(b)(4)





Sterilization Qualification Report of the MediGuide (b)(4)

(b)(4)

4.0 Reference Documents

Document Number	Document Title
(b)(4)	

5.0 Deviations from the Qualification Protocol

(b)(4)



Sterilization Qualification Report of the MediGuide (b)(4)

(b)(4)

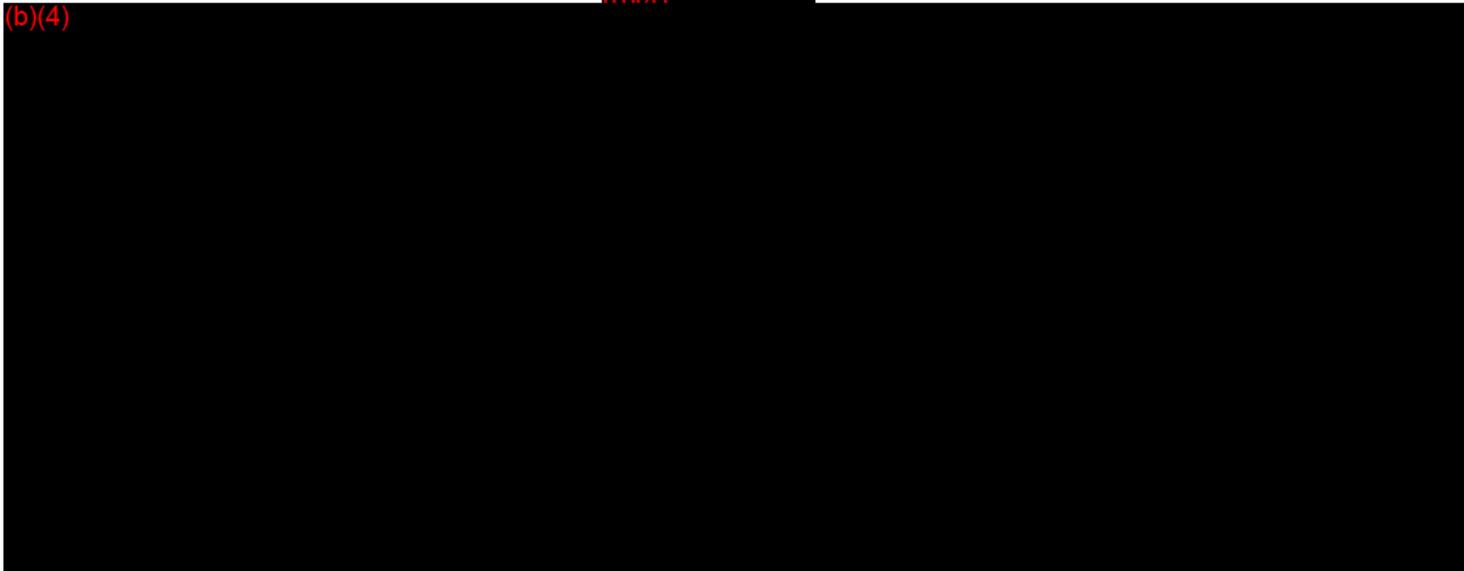
6.0 Results

(b)(4)



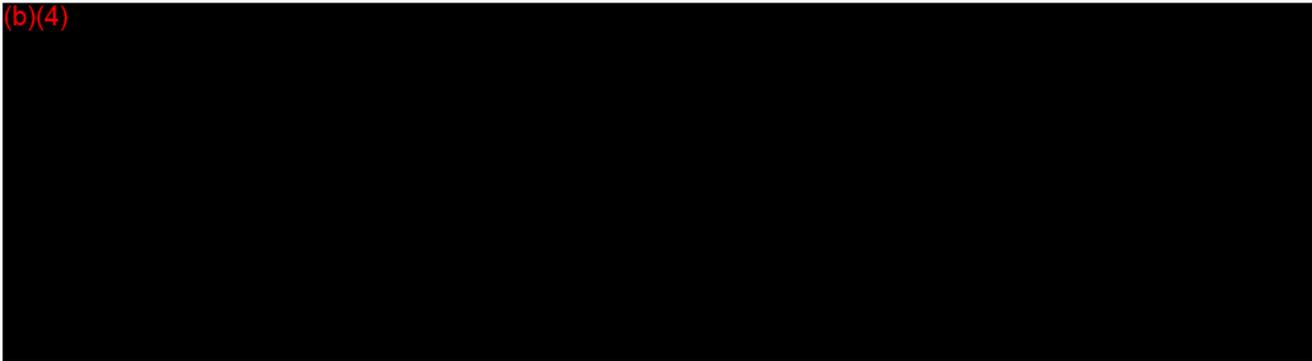
Sterilization Qualification Report of the MediGuide (b)(4)

(b)(4)



7.0 Conclusion

(b)(4)



Attachments

- Attachment #1 MediGuide (b)(4) Report
- Attachment #2 MediGuide (b)(4) Validation (b)(4)
- Attachment #3 MediGuide (b)(4) Testing (b)(4) Report

Appendix 7

 <p>ST. JUDE MEDICAL MORE CONTROL. LESS RISK.</p>	<p>No. (b)(4) Division: Atrial Fibrillation Document Type: Sterilization Validation Version: (b)(4) Page: 1 of 8</p>
<p>Sterilization Qualification Report for adoption of the MediGuide Guidewire (b)(4)</p>	
<p>Report: (b)(4) Version (b)(4)</p>	
<p>Protocol Number: (b)(4)</p>	
<p>Version History</p> <p>New document (b)(4)</p>	

Version history and electronic signatures are contained in Windchill



Sterilization Qualification Report for adoption of the MediGuide Guidewire (b)(4)

Executive Summary

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

1.0 Purpose

(b)(4)



ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

(b)(4) Version (b)(4)
Sterilization Validation
3 of 8

Sterilization Qualification Report for adoption of the MediGuide Guidewire (b)(4)

(b)(4)

2.0 Scope

(b)(4)

[Redacted content]

(b)(4)

[Redacted content]

4.0 Reference Documents

Document Number	Document Title
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(b)(4)

[Redacted content]



Sterilization Qualification Report for adoption of the MediGuide Guidewire (b)(4)

(b)(4)

Document Number	Document Title
-----------------	----------------

(b)(4)

(b)(4)	
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5.0 Deviations from the Qualification Protocol

(b)(4)

Table 2. Deviations from Protocol 90067664

Deviation Number	Report	Details of Deviation From Protocol
------------------	--------	------------------------------------

(b)(4)

(b)(4)		
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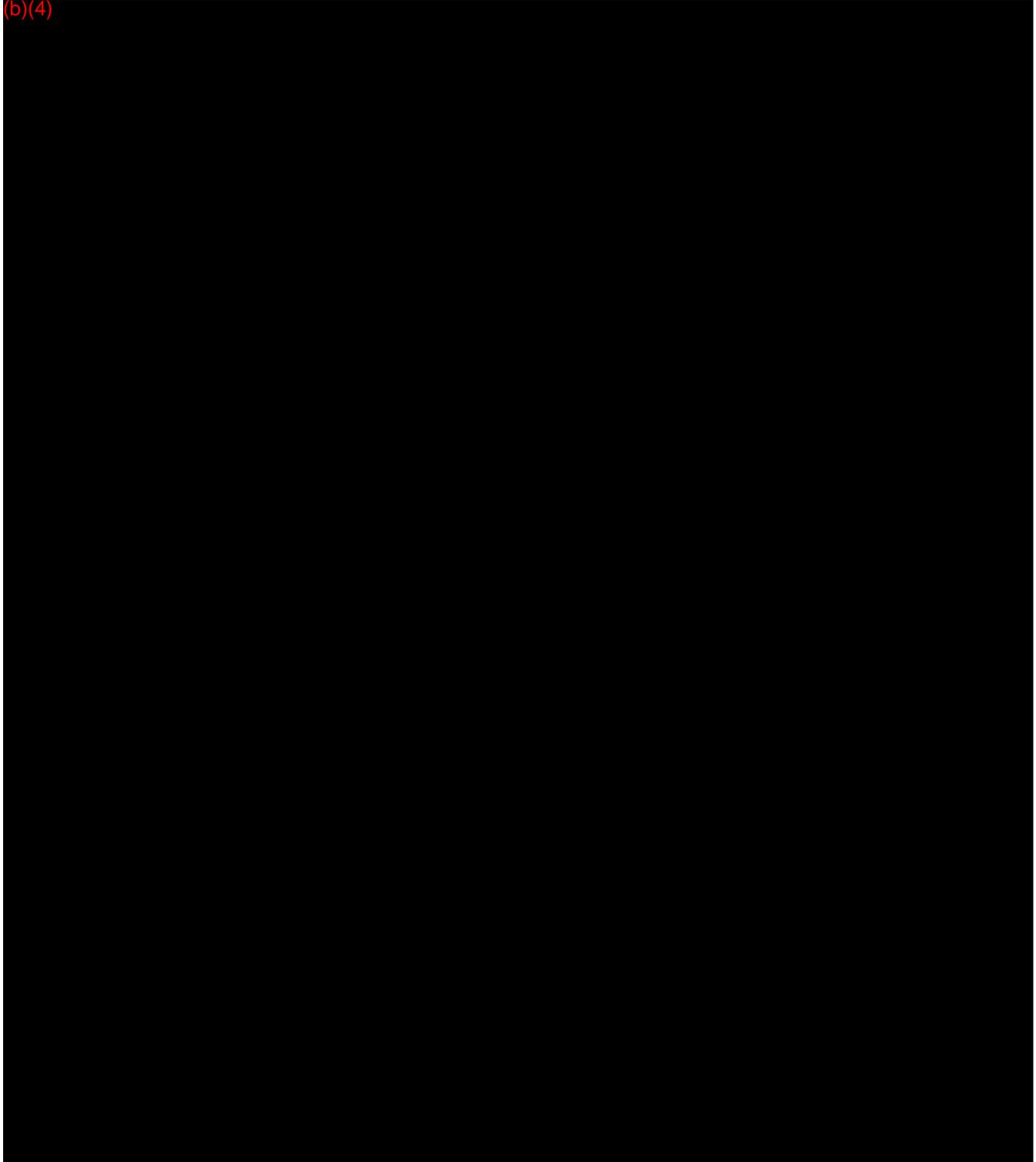
(b)(4) Version (b)(4)
Sterilization Validation
5 of 8

Sterilization Qualification Report for adoption of the MediGuide Guidewire (b)(4)

(b)(4)

6.0 Results

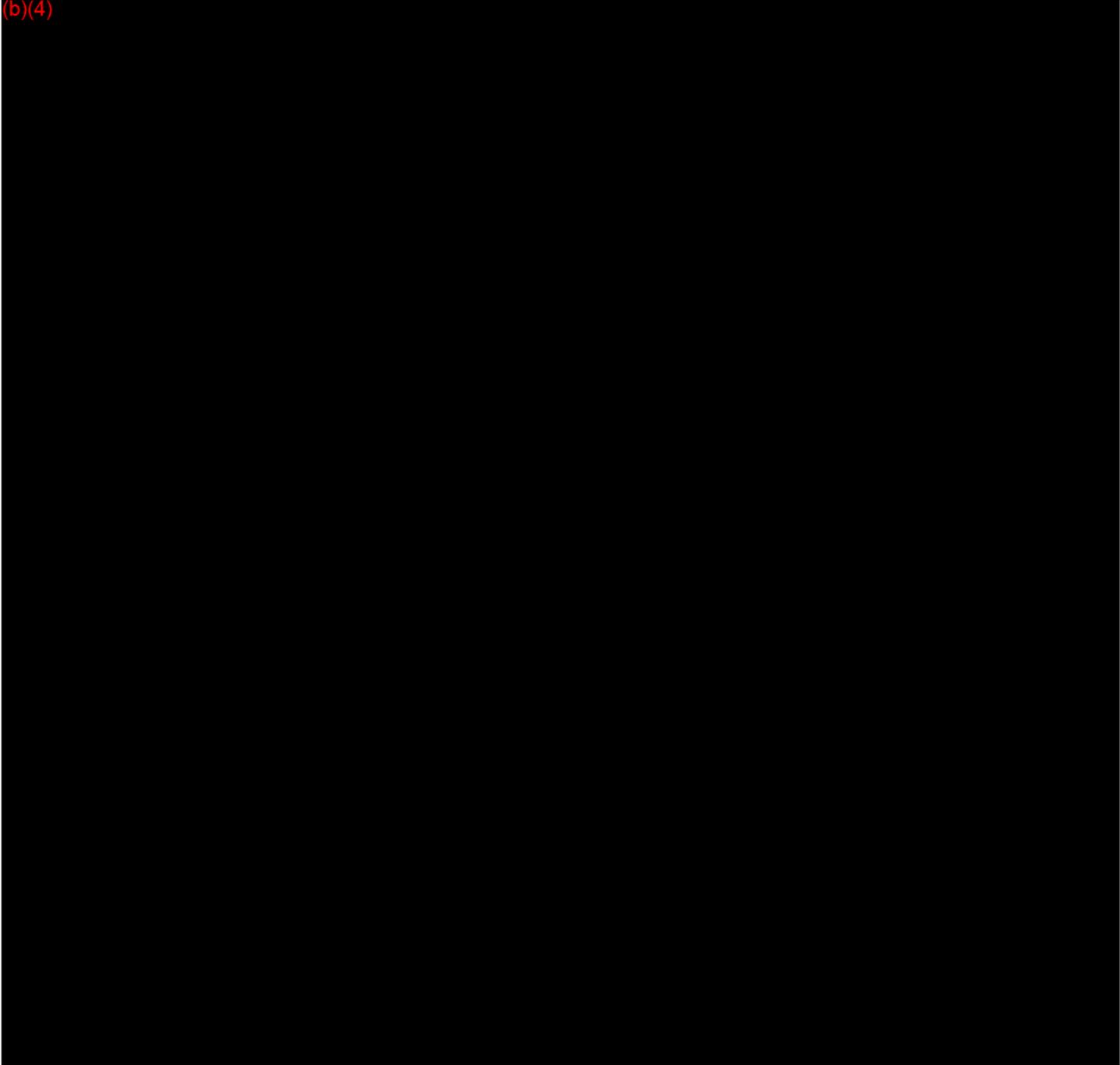
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Sterilization Qualification Report for adoption of the MediGuide Guidewire (b)(4)

(b)(4)



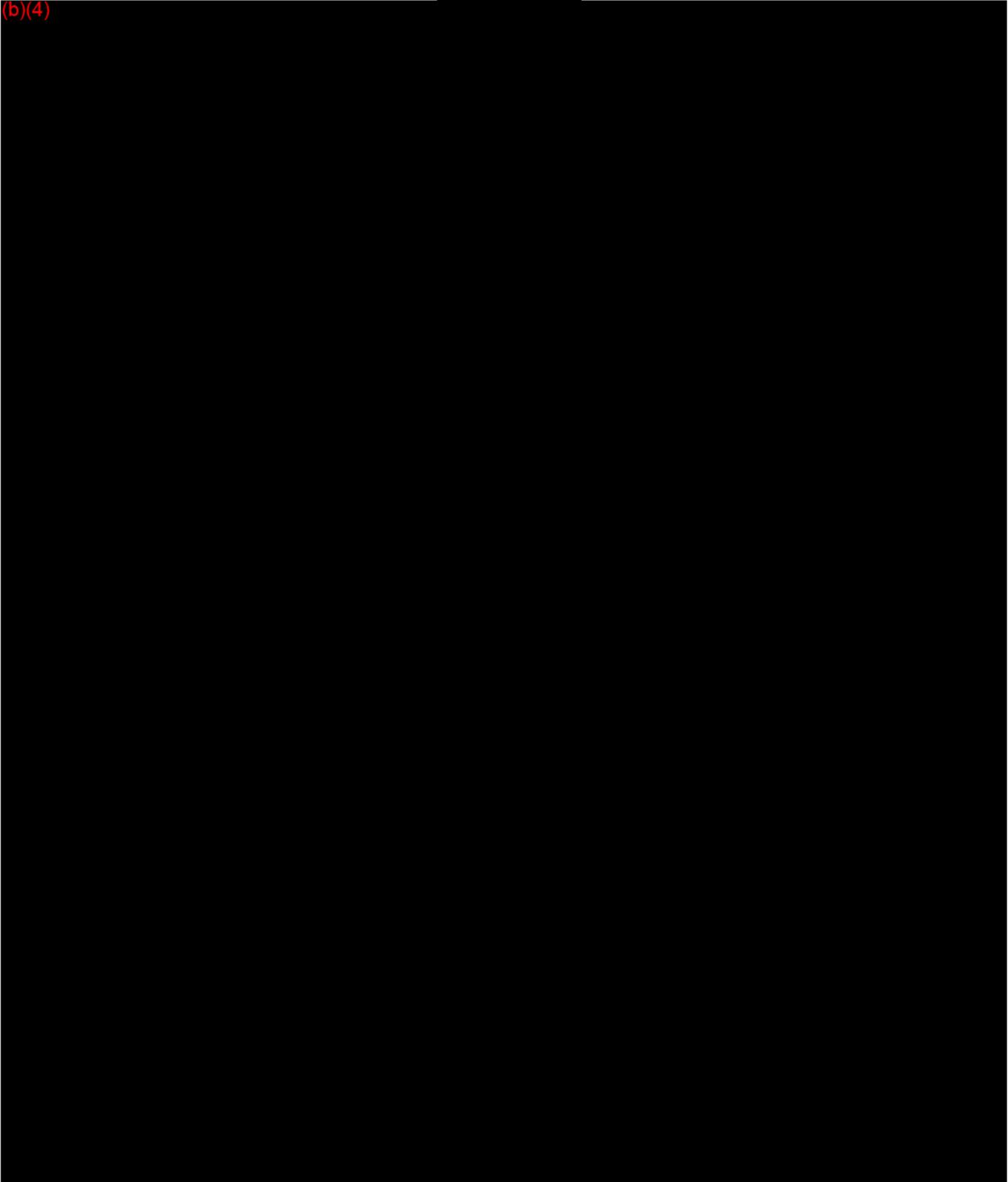


(b)(4) Version (b)(4)
Sterilization Validation
7 of 8

Sterilization Qualification Report for adoption of the MediGuide Guidewire (b)(4)

(b)(4)

(b)(4)

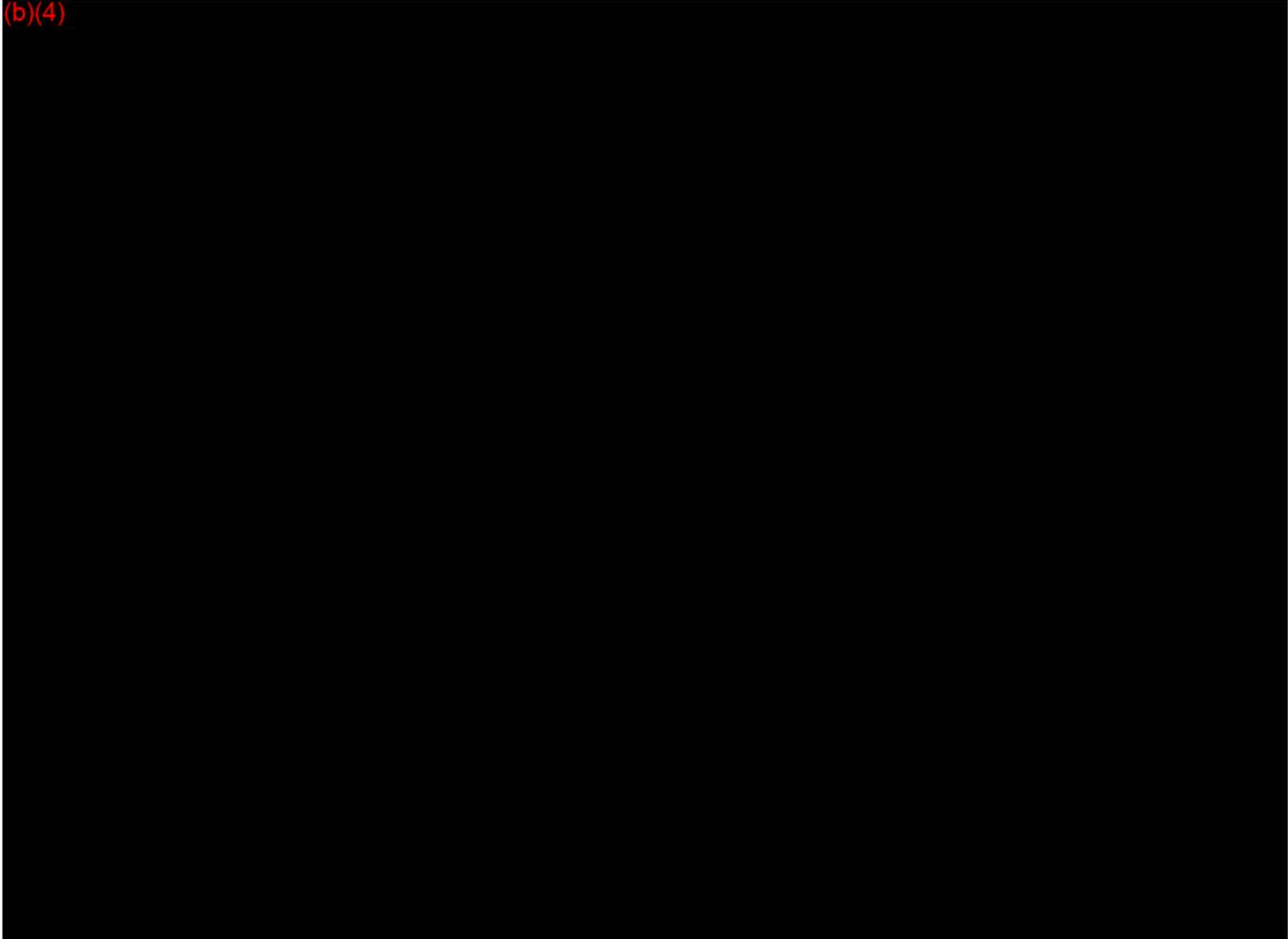




ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

(b)(4) Version (C)
Sterilization Validation
8 of 8

(b)(4)



Appendix 8

	ST. JUDE MEDICAL MORE CONTROL. LESS RISK.	NO. (b)(4) Division: Atrial Fibrillation Document Type: Sterilization Validation Version: (b)(4) Page: 1 of 7
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Sterilization Qualification Report for adoption of the MediGuide Guidewire

Report: (b)(4) Version: (b)(4)

Protocol Number: (b)(4)

Version History

New document (b)(4)

Version history and electronic signatures are contained in Windchill



Sterilization Qualification Report for adoption of the MediGuide Guidewire

(b)(4)

Executive Summary

(b)(4)

(b)(4)



Sterilization Qualification Report for adoption of the MediGuide Guidewire

(b)(4)

2.0 Scope

(b)(4)

4.0 Reference Documents

Document Number	Document Title
-----------------	----------------

(b)(4)



Sterilization Qualification Report for adoption of the MediGuide Guidewire

(b)(4)

Document Number

Document Title

(b)(4)

5.0 Deviations from the Qualification Protocol

(b)(4)

(b)(4)

6.0 Results

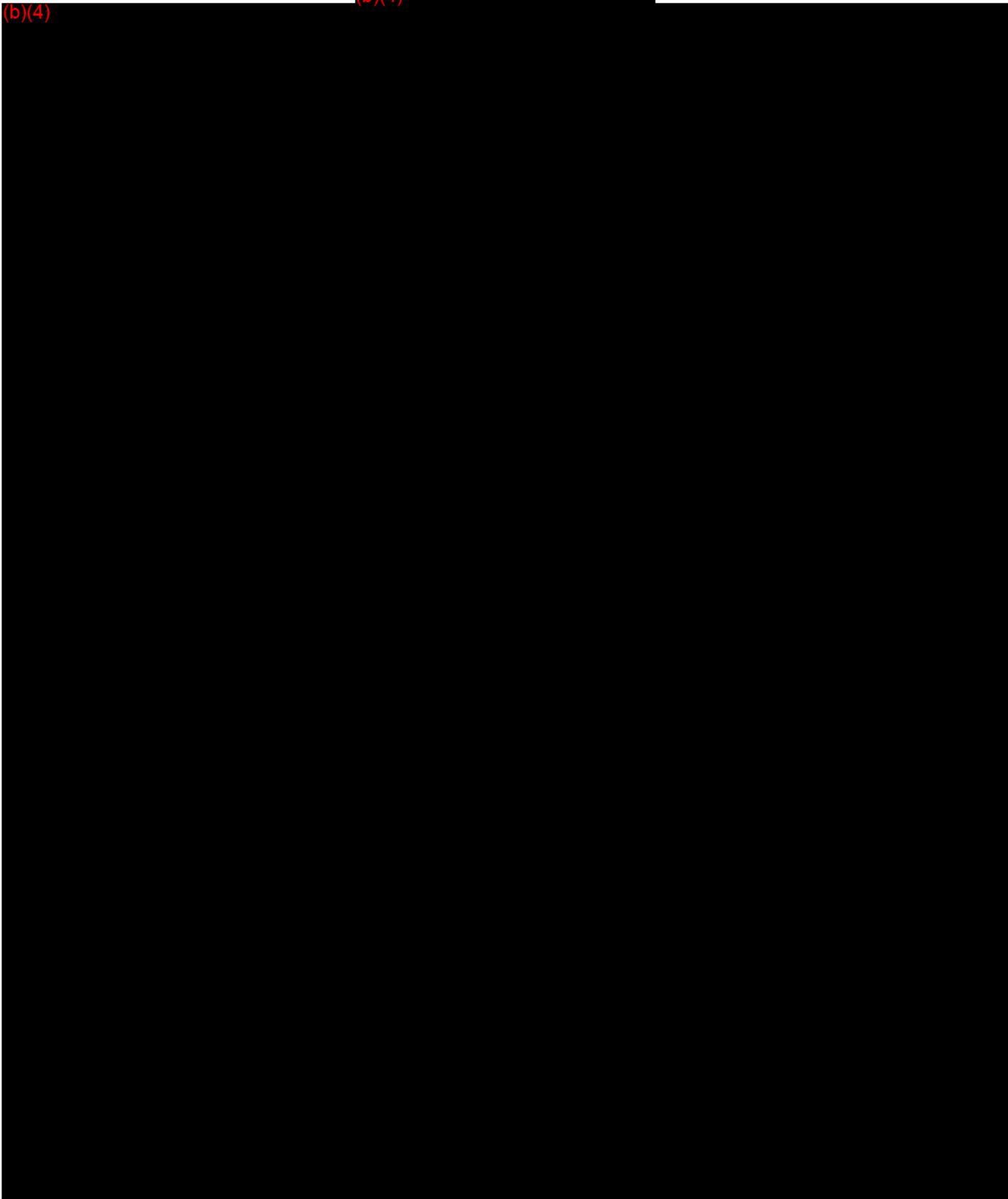
(b)(4)



Sterilization Qualification Report for adoption of the MediGuide Guidewire

(b)(4)

(b)(4)





Sterilization Qualification Report for adoption of the MediGuide Guidewire

(b)(4)

(b)(4)

Attachments

- Attachment 1. (b)(4) (b) data
- Attachment 2. (b)(4) sterility results
- Attachment 3. (b)(4) sterility results
- Attachment 4. (b)(4)
- Attachment 5. MediGuide Guidewire Connector (b)(4) report

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

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: January 6, 2012	
		Page 1(23)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR - (b)(4) Test Report for (b)(4) MediGuide Enabled Guidewire Model numbers: DS2M027, DS2M028, DS2M029			
1.0 CONCURRENCE			
Author Name/Title:	Signature:	Date:	
(b)(6)	(b)(6)	1/25/12	
Design Assurance Engineer			
Approved by/Title:			
Colleen Canan Regulatory Affairs (US)	<i>Colleen</i>	19-JAN-2012	
Approved by/Title:			
(b)(6)	See Attached		
Regulatory Affairs (OUS)			
Approved By/Title:			
(b)(6)	See Attached		
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Approved By/Title:			
(b)(6)	See Attached		
Engineering Manager (Development)			
Approved By/Title:	(b)(6)		
(b)(6)		1/24/12	
Manager, QA Operations			

(b)(4) (b)(4) MediGuide Enabled Guidewire

 ST. JUDE MEDICAL MORE CONTROL. LESS RISK.		Date: January 6, 2012	
		Page 1(23)	
Document Number (b)(4)		Revision: (b)(4)	
Document Title: QTR – (b)(4) Test Report for (b)(4) MediGuide Enabled Guidewire Model numbers: DS2M027, DS2M028, DS2M029			
1.0 CONCURRENCE			
Author Name/Title:	Signature:	Date:	
(b)(6) Design Assurance Engineer			
Approved by/Title:			
Colleen Canan Regulatory Affairs (US)			
Approved by/Title:	(b)(6)	1/26/12	
(b)(6) Regulatory Affairs (OUS)			
Approved By/Title:			
(b)(6) Development Engineer			
Approved By/Title:			
(b)(6) Engineering Manager (Development)			
Approved By/Title:			
(b)(6) Manager, QA Operations			

(b)(4) [Redacted] (b)(4) [Redacted] MediGuide Enabled Guidewire

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: January 6, 2012
		Page 1(23)
Document Number: (b)(4) [Redacted]	Revision: (b)(4) [Redacted]	
Document Title: QTR – (b)(4) [Redacted] Test Report for (b)(4) [Redacted] MediGuide Enabled Guidewire Model numbers: DS2M027, DS2M028, DS2M029		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6) [Redacted] Design Assurance Engineer		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)		
Approved by/Title:		
(b)(6) [Redacted] Regulatory Affairs (OUS)		
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(b)(6) [Redacted] Development Engineer		
Approved By/Title:	(b)(6) [Redacted]	19 Jan 2012
(b)(6) [Redacted] Engineering Manager (Development)		
Approved By/Title:		
(b)(6) [Redacted] Manager, QA Operations		

(b)(4) (b)(4) MediGuide Enabled Guidewire

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(b)(4) (b)(4) QTR for (b)(4) MediGuide Enabled Guidewire

QTR (b)(4) Date: January 6, 2012
(b)(4) Test Report for (b)(4) MediGuide Enabled Guidewire
Model numbers: DS2M027, DS2M028, DS2M029

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

(b)(4)

(b)(4)

(b)

(4)

QTR for MediGuide Enabled Guidewire

(b)(4)

TEST RATIONALE

(b)(4)

Table 2 Tests Included in this Test Report

Test	Model	Rationale for Model Chosen	Requirements in Product Spec Section
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(b)(4)



ST. JUDE MEDICAL
MEDICAL CONTROL SYSTEMS

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4(23)

Design Assurance

(b)(4)

(b)(4)

QTR for CRM MediGuide Enabled Guidewire

(b)(4)

[Redacted content]

(b)(4)

Study:

(b)(4)

[Redacted content]



ST. JUDE MEDICAL
MOST CONFIDENTIAL

Company Confidential

5(23)

Design Assurance

(b)(4) Testing [redacted] (b)(4) QTR for CRM MediGuide Enabled Guidewire

(b)(4) Testing [redacted]

4.1 SUMMARY OF RESULTS

(b)(4) Testing [redacted]

4.2 CONCLUSIONS

(b)(4) Testing [redacted]

5.0 ASSOCIATED DOCUMENTS

	Document #	Rev #*	Document Title
5.1	(b)(4) Testing		[redacted]
5.2			[redacted]
5.3			[redacted]
5.4			[redacted]
5.5			[redacted]
5.6			[redacted]
5.7			[redacted]

(b)(4) Testing (b)(4) TR for CRM MedGuide Enabled Guidewire

5.8	(b)(4) Testing
5.9	(b)(4) Testing
5.10	(b)(4) Testing
5.11	(b)(4) Testing
5.12	(b)(4) Testing
5.13	(b)(4) Testing
5.14	(b)(4) Testing
5.15	(b)(4) Testing
5.16	(b)(4) Testing
5.17	(b)(4) Testing
5.18	(b)(4) Testing

6.0 ASSOCIATED TEST EQUIPMENT

	Description	Applicable Tests
6.1	(b)(4) Testing	(b)(4) Testing
6.2	(b)(4) Testing	(b)(4) Testing
6.3	(b)(4) Testing	(b)(4) Testing
6.4	(b)(4) Testing	(b)(4) Testing
6.5	(b)(4) Testing	(b)(4) Testing
6.6	(b)(4) Testing	(b)(4) Testing
6.7	(b)(4) Testing	(b)(4) Testing
6.8	(b)(4) Testing	(b)(4) Testing
6.9	(b)(4) Testing	(b)(4) Testing
6.10	(b)(4) Testing	(b)(4) Testing

(b)(4) Testing (b)(4) Testi QTR for CRM MediGuide Enabled Guidewire

(b)(4) Testing

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

Test Flow	Description	ID
-----------	-------------	----

(b)(4) Testing (b)(4) Testing

(b)(4) Testing

8.0 SAMPLE SIZE JUSTIFICATION

(b)(4) Testing

9.0 TEST SEQUENCE

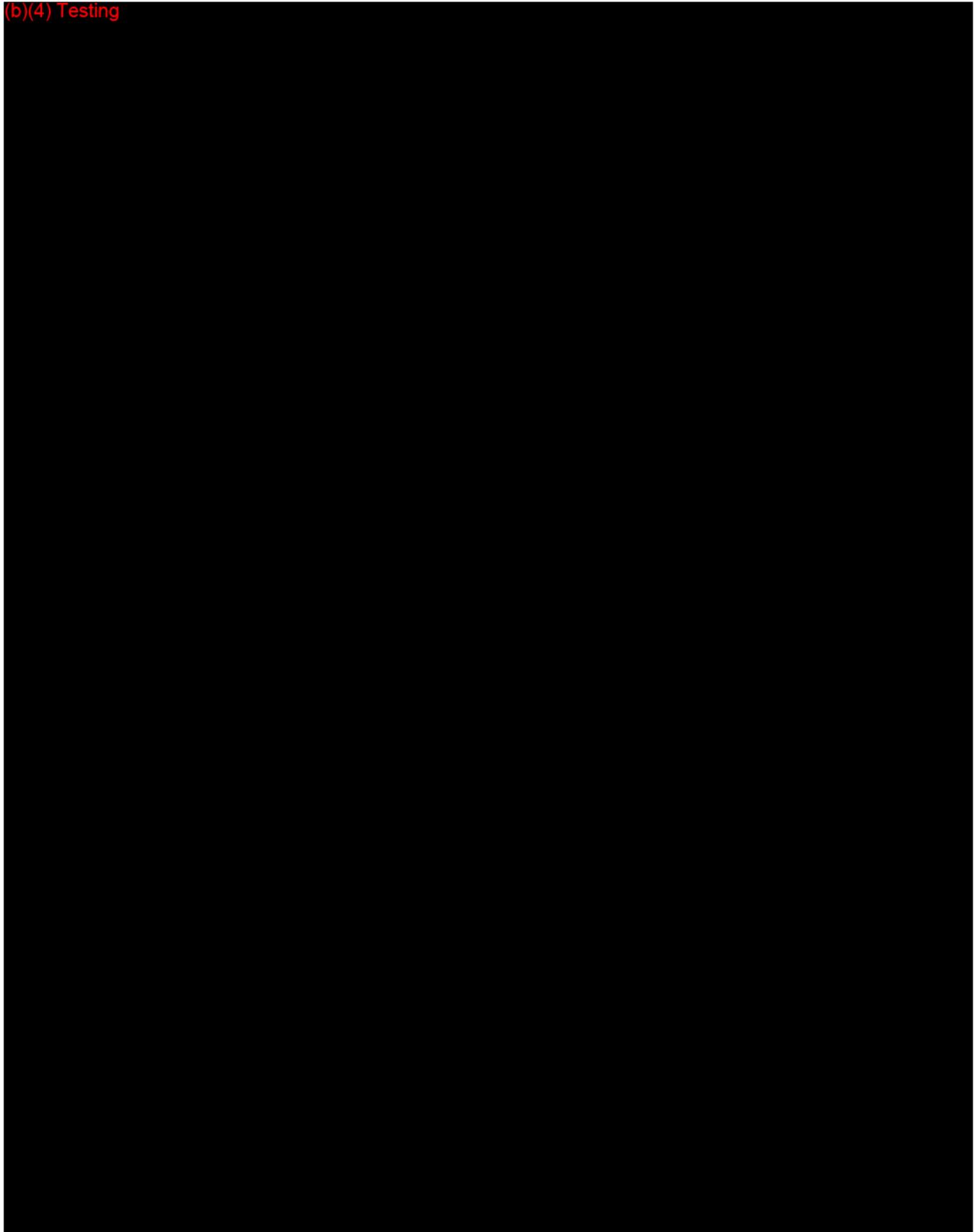
(b)(4) Testing

(b)(4) Testing

(b)(4)
Testin

TR for CRM MediGuide Enabled Guidewire

(b)(4) Testing



(b)(4)
Testing

(b)(4)
Testing

QTR for CRM MediGuide Enabled Guidewire

10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4) Testing (b)(4) Testi QTR for CRM MediGuide Enabled Guidewire

(b)(4)

TEST RESULTS

(b)(4)

10.2 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) Testing

(b)(4) TR for CRM MediGuide Enabled Guidewire

10.3

(b)(4) TEST

PURPOSE

(b)(4)

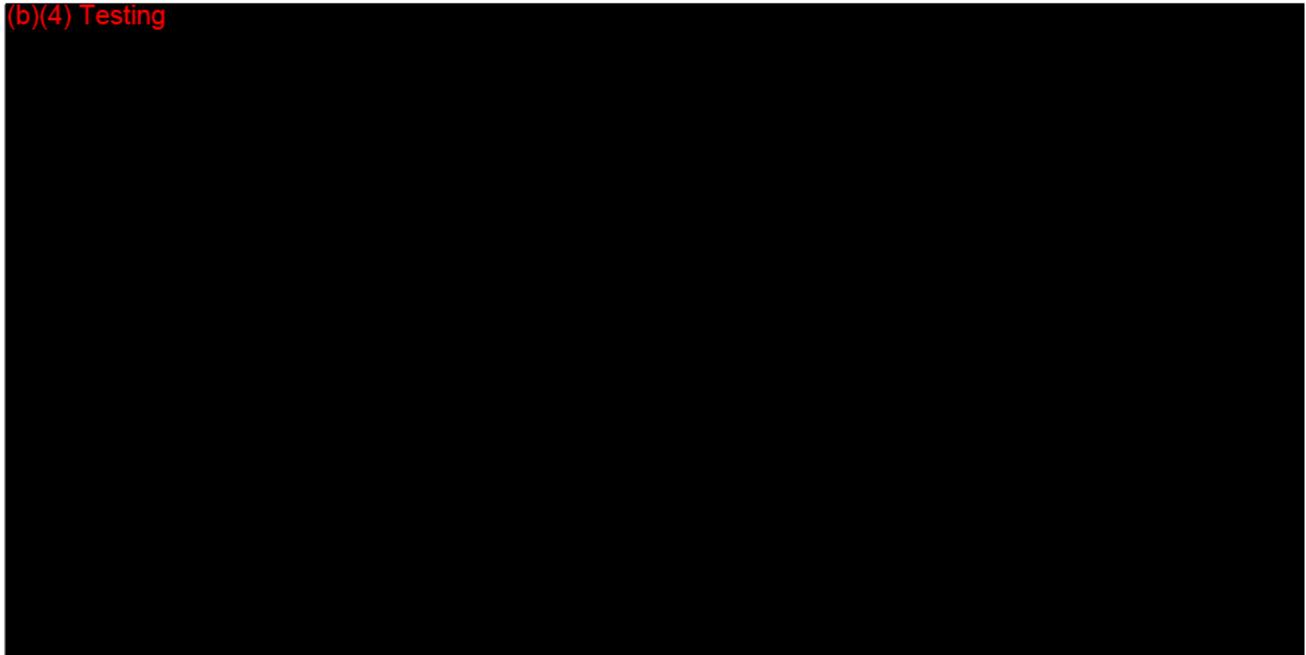
TEST REQUIREMENT

(b)(4)

(b)(4)
Testing

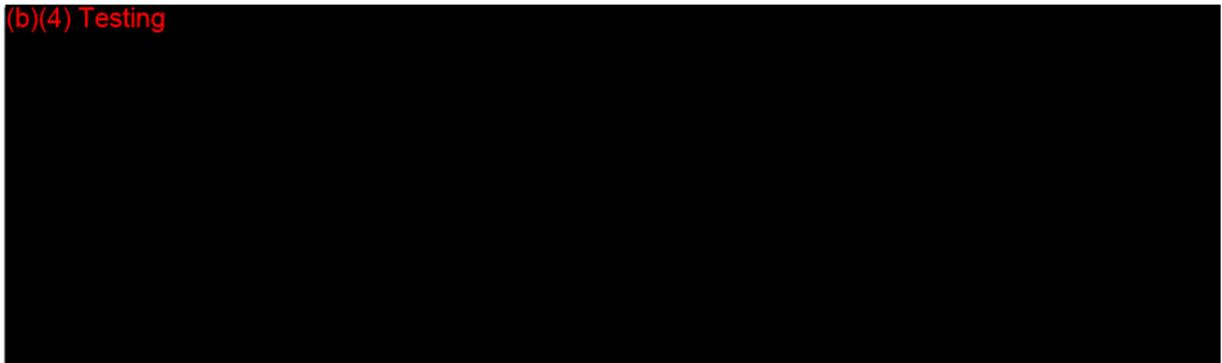
(b)(4)
Testing TR for CRM MediGuide Enabled Guidewire

(b)(4) Testing



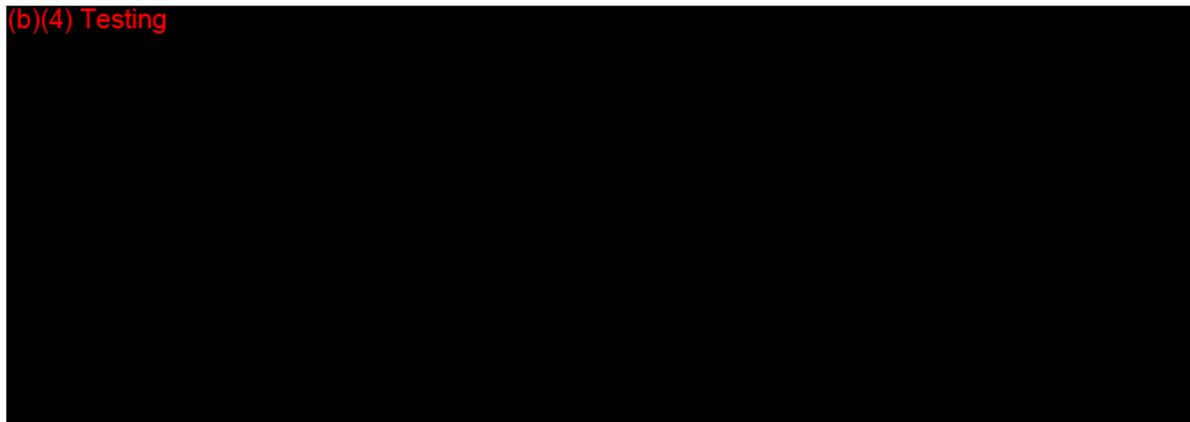
ACCEPTANCE CRITERIA

(b)(4) Testing



TEST RESULTS

(b)(4) Testing



(b)(4) Testing [redacted] (b)(4) Testing TR for CRM MediGuide Enabled Guidewire

10.4 (b)(4) Testing TEST

PURPOSE

(b)(4) Testing [redacted]

TEST REQUIREMENT

(b)(4) Testing [redacted]

ACCEPTANCE CRITERIA

(b)(4) Testing [redacted]

TEST RESULTS

(b)(4) Testing [redacted]

10.5 (b)(4) Testing TEST

PURPOSE

(b)(4) Testing [redacted]

TEST REQUIREMENTS

(b)(4) Testing [redacted]

(b)(4)

(b)(4)

QTR for CRM MediGuide Enabled Guidewire

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4) Testing

TEST RESULTS

(b)(4) Testing

10.6

(b)(4)

(b)(4) Testing

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4) Testing



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15(23)

Design Assurance

(b)(4) Testing

(b)(4) Testin

QTR for CRM MediGuide Enabled Guidewire

(b)(4) Testing

TEST RESULTS

(b)(4) Testing

ANALYSIS

(b)(4) Testing

CORRECTIVE ACTION

(b)(4) Testing

10.7 (b)(4) Testing TEST

PURPOSE

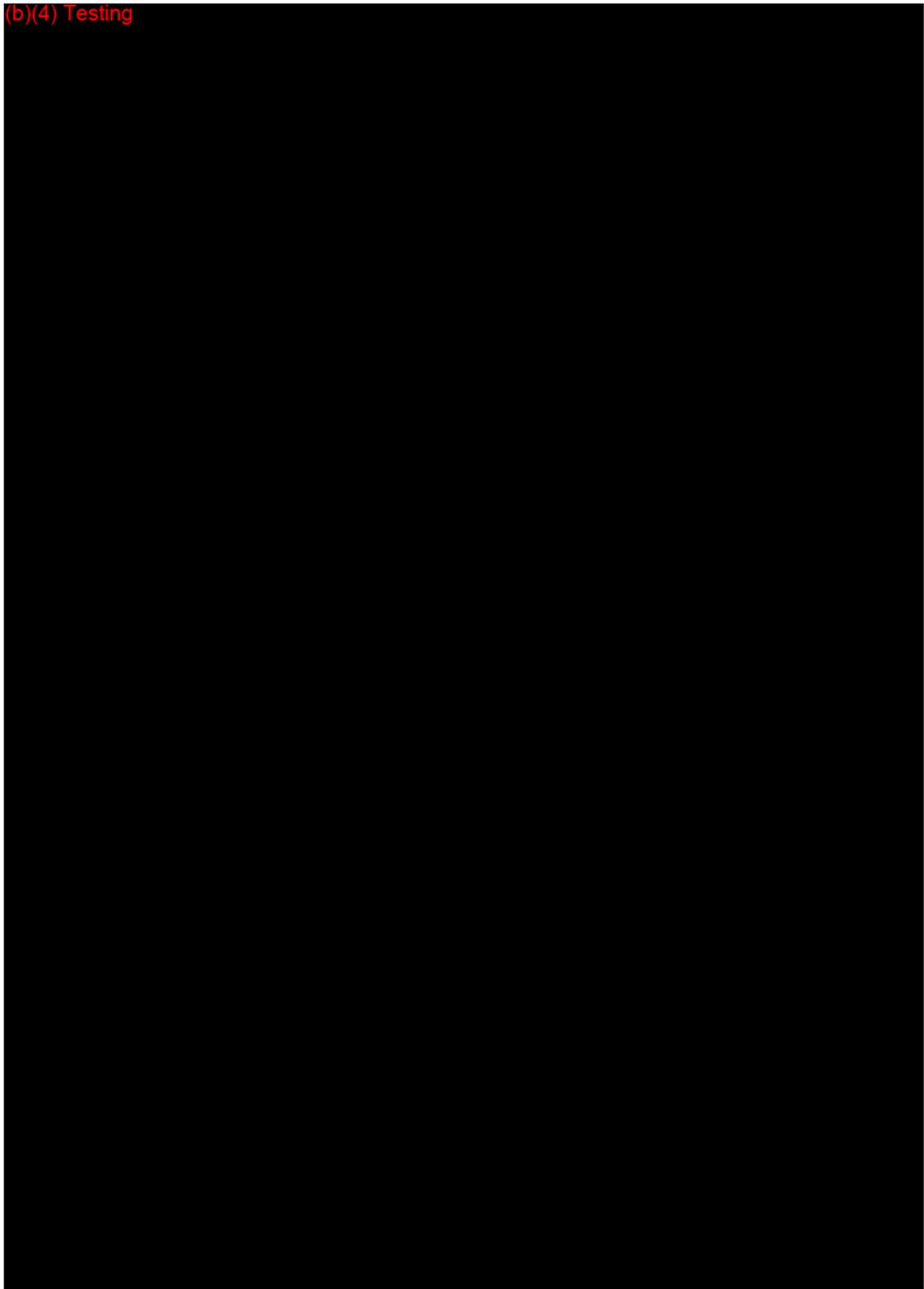
(b)(4) Testing

(b)(4)
Testing

(b)(4) QTR for CRM MediGuide Enabled Guidewire

TEST REQUIREMENT

(b)(4) Testing

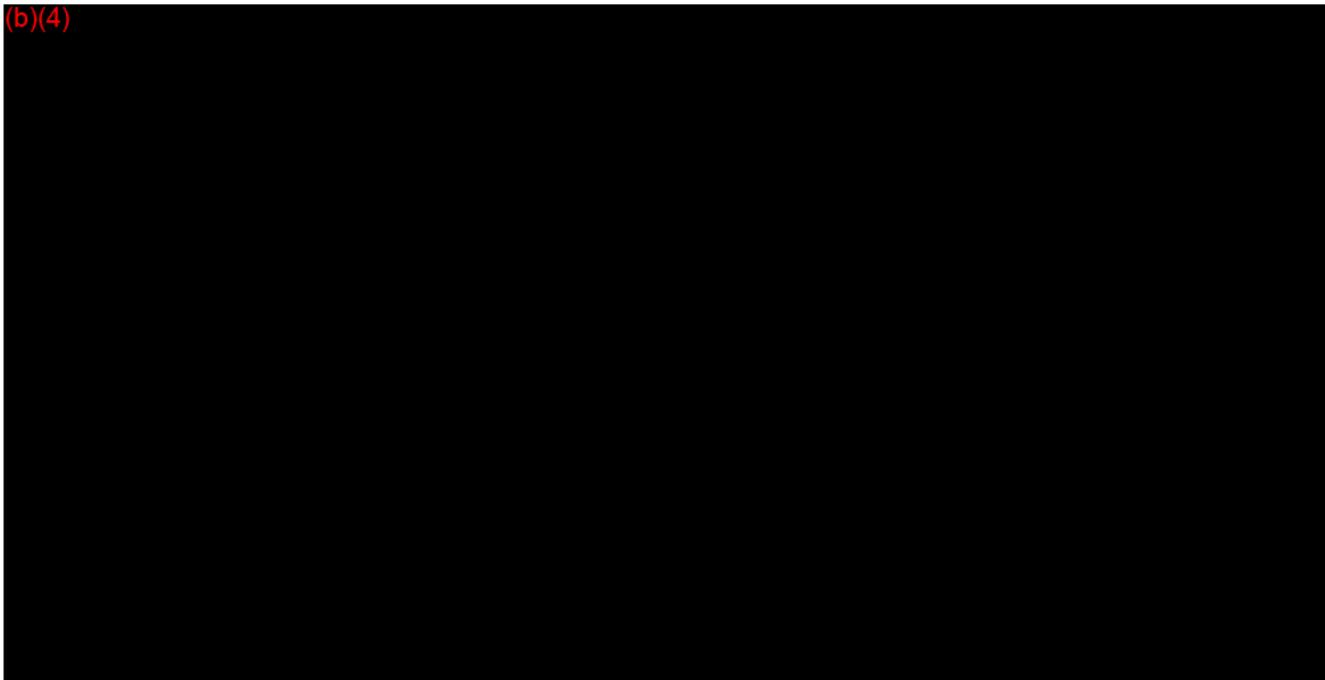


(b)(4)

(b)(4)
Testin

QTR for CRM MediGuide Enabled Guidewire

(b)(4)



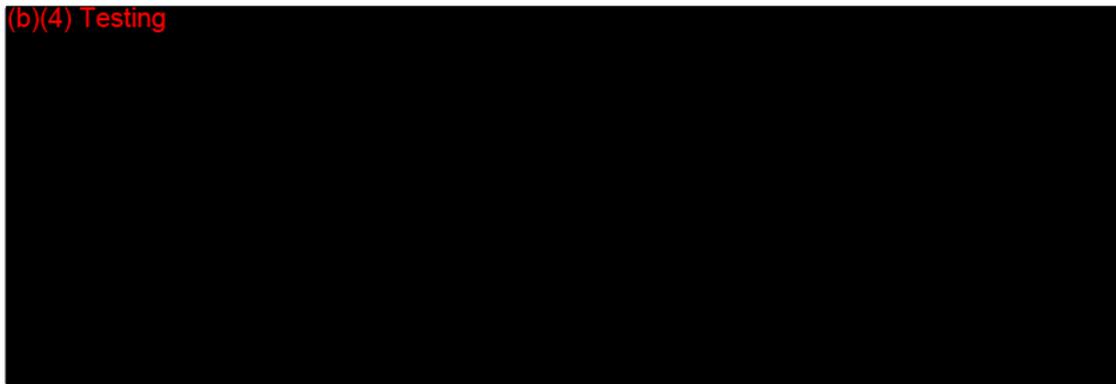
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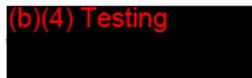
TEST RESULTS

(b)(4) Testing



10.8

(b)(4) Testing



TEST

PURPOSE

(b)(4) Testing



TEST REQUIREMENT

(b)(4) Testing



(b)(4) Testing

(b)(4)

QTR for CRM MediGuide Enabled Guidewire

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.9

(b)(4)
(b)(5)(4)

TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4)

(b)(4)

QTR for CRM MediGuide Enabled Guidewire

(b)(4)

[Redacted content]

ACCEPTANCE CRITERIA

(b)(4)

[Redacted content]

TEST RESULTS

(b)(4)

[Redacted content]

10.10 GUIDEWIRE

(b)(4)

[Redacted content]

TEST

PURPOSE

(b)(4)

[Redacted content]

TEST REQUIREMENT

(b)(4)

[Redacted content]



ST. JUDE MEDICAL
MOORE CONSTRUCTION ASSOCIATES

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20(23)

Design Assurance

(b)(4) (b)(4) QTR for CRM MediGuide Enabled Guidewire

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

60038227 (b)(4) QTR for CRM MediGuide Enabled Guidewire

(b)(4)

TEST RESULTS

(b)(4)

10.12 (b)(4)

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4) Testing

TEST RESULTS

(b)(4) Testing

10.13 (b)(4) Testing (4) GUIDEWIRE

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

60038227

(b)(4)

QTR for CRM MediGuide Enabled Guidewire

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4) Testing

TEST RESULTS

(b)(4) Testing

10.14

(b)(4) Testing

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

ACCEPTANCE CRITERIA

(b)(4) Testing

TEST RESULTS

(b)(4) Testing

Appendix 10

(b)(4) QTR - (b)(4) Test Report of MediGuide™ (b)(4)

 ST. JUDE MEDICAL MORE CONTROL. LESS RISK.		Date: January 7, 2012
		Page 1(25)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR - (b)(4) Test Report of MediGuide™ (b)(4)		
Model number: DS2M031		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6)	(b)(6)	1/25/12
Design Assurance		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)	<i>C Canan</i>	24-JAN-2012
Approved by/Title:		
(b)(6)	<i>See Attached</i>	
Regulatory Affairs (OUS)		
Approved By/Title:	(b)(6)	26 Jan 2012
(b)(6)		
Development		
Approved By/Title:		26 Jan 2012
(b)(6)		
Program/ Development Management		
Approved By/Title:		1/24/12
(b)(6)		
Design Assurance Management		

(b)(4) QTR - (b)(4) Test Report of MediGuide™ (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL LESS RISK</small>		Date: January 7, 2012
		Page 1(25)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR - (b)(4) Test Report of MediGuide™ (b)(4)		
Model number: DS2M031		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6) Design Assurance		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)		
Approved by/Title:	(b)(6)	
(b)(6) Regulatory Affairs (OUS)		1/26/12
Approved By/Title:		
(b)(6) Development		
Approved By/Title:		
(b)(6) Program/ Development Management		
Approved By/Title:		
(b)(6) Design Assurance Management		

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(b)(4) Testing QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

60039764 Date: January 7, 2012
QTR - (b)(4) Testing Test Report of MediGuide™
(b)(4) Testing
Model number: DS2M031

3.0 PURPOSE

(b)(4) Testing

4.0 SCOPE

(b)(4) Testing

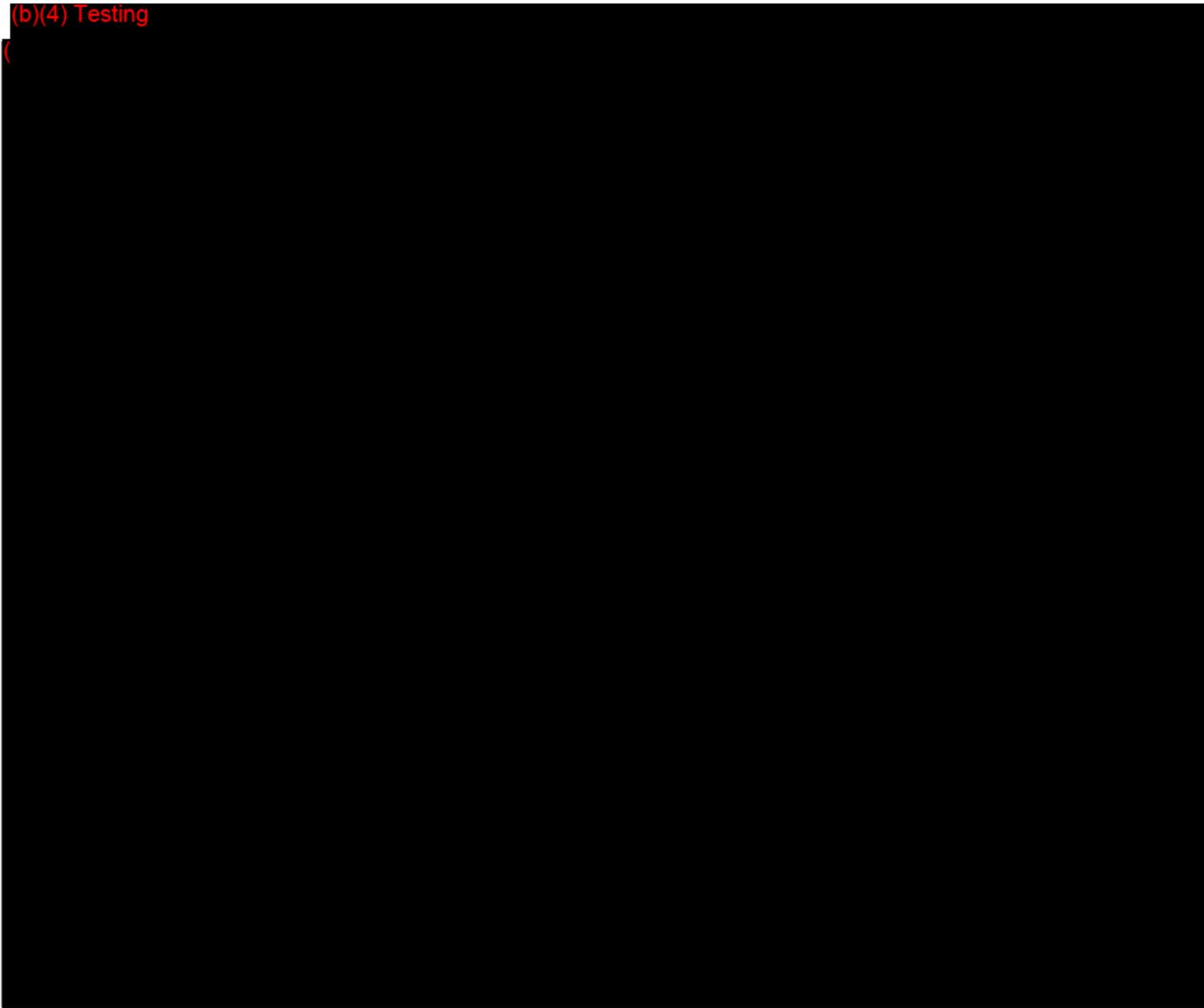
(b)(4) Testing QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

Table 2 Tests Included in this Test Report

Test #	Test	Requirement/ Specification
10.1	(b)(4) Testing	
10.2		
10.3		
10.4		
10.5		
10.6		
10.7		
10.8		
10.9		
10.10		
10.11		

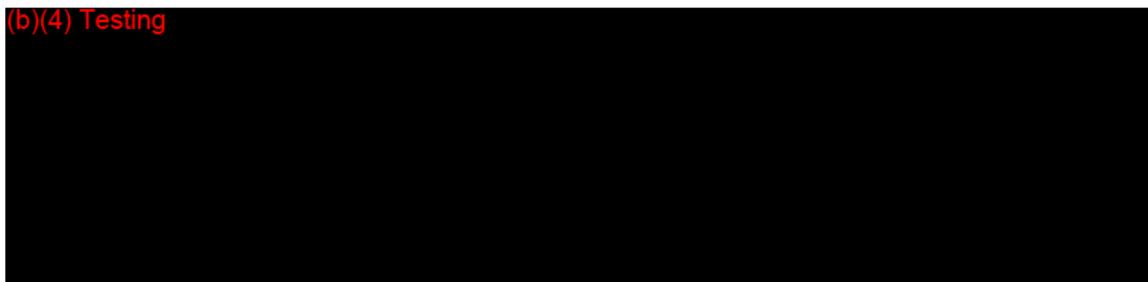
(b)(4) Testing

(b)(4) Testing



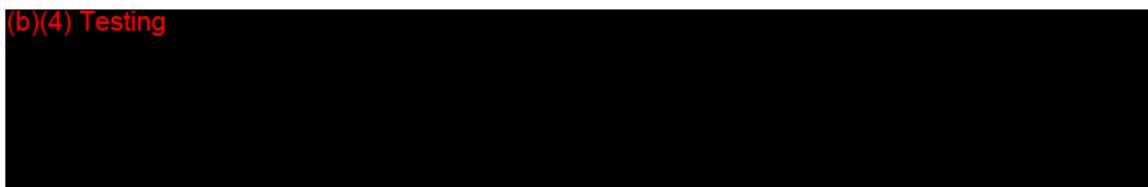
4.1 SUMMARY OF RESULTS

(b)(4) Testing



4.2 CONCLUSIONS

(b)(4) Testing



(b)(4) QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

(b)(4) Testing

5.0 ASSOCIATED DOCUMENTS

Table 3 Associated Documents

Document #	Rev #*	Document Title
5.1		(b)(4) Testing
5.2		
5.3		
5.4		
5.5		
5.6		
5.7		
5.8		
5.9		
5.10		
5.11		
5.12		
5.13		
5.14		
5.15		
5.16		
5.17		
5.18		

(b)(4) Testing QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

(b)(4) Testing

6.0 ASSOCIATED TEST EQUIPMENT

Table 4 Associated Test Equipment

	Description	Applicable Tests
6.1	(b)(4) Testing	
6.2		
6.3		
6.4		
6.5		
6.6		
6.7		

(b)(4) Testing

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4) Testing

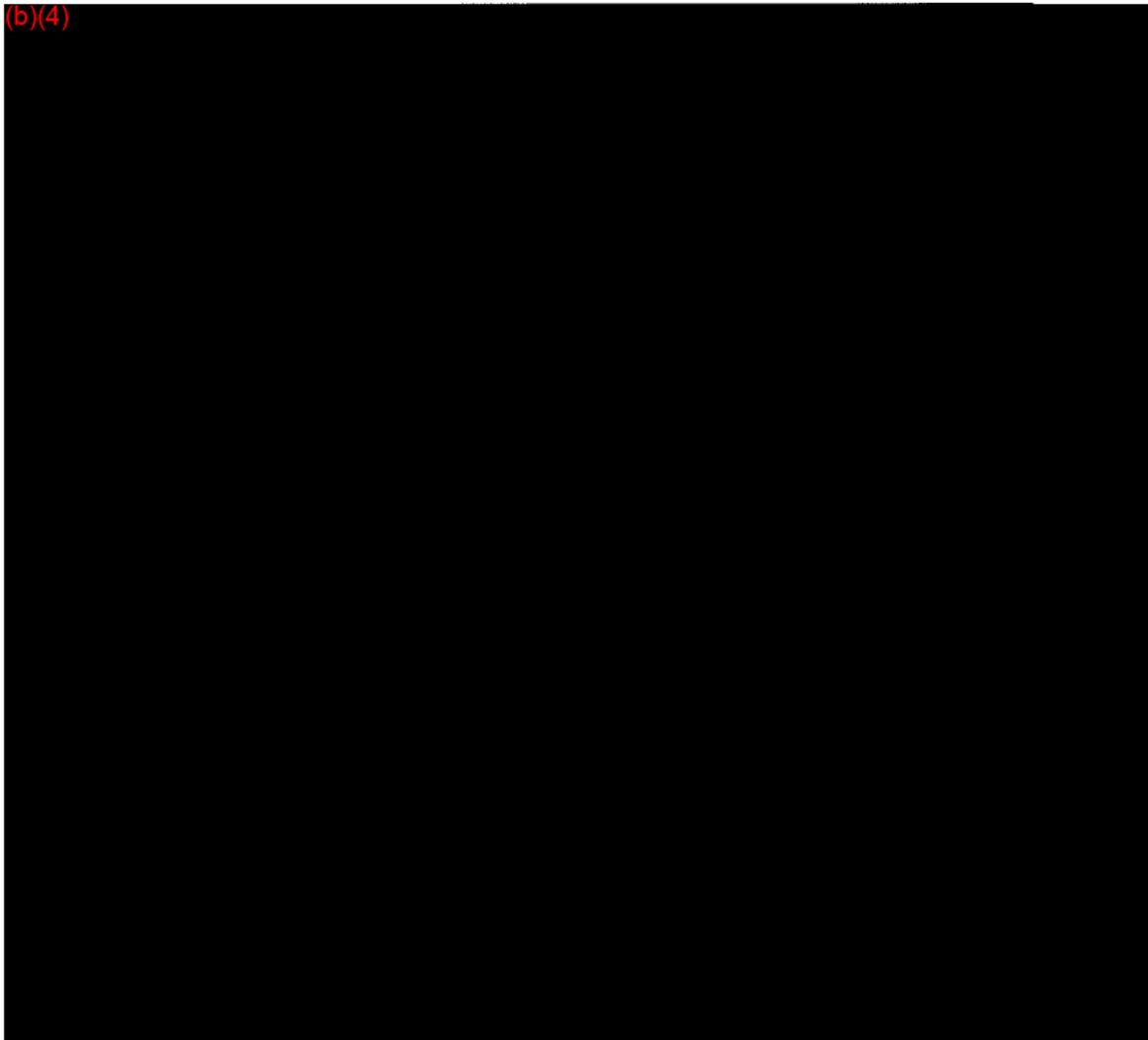
8.0 SAMPLE SIZE JUSTIFICATION

(b)(4) Testing

9.0 TEST SEQUENCE (b)(4) Testing

(b)(4) Testing

FUNCTIONAL TEST FLOW



10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4)
Testing

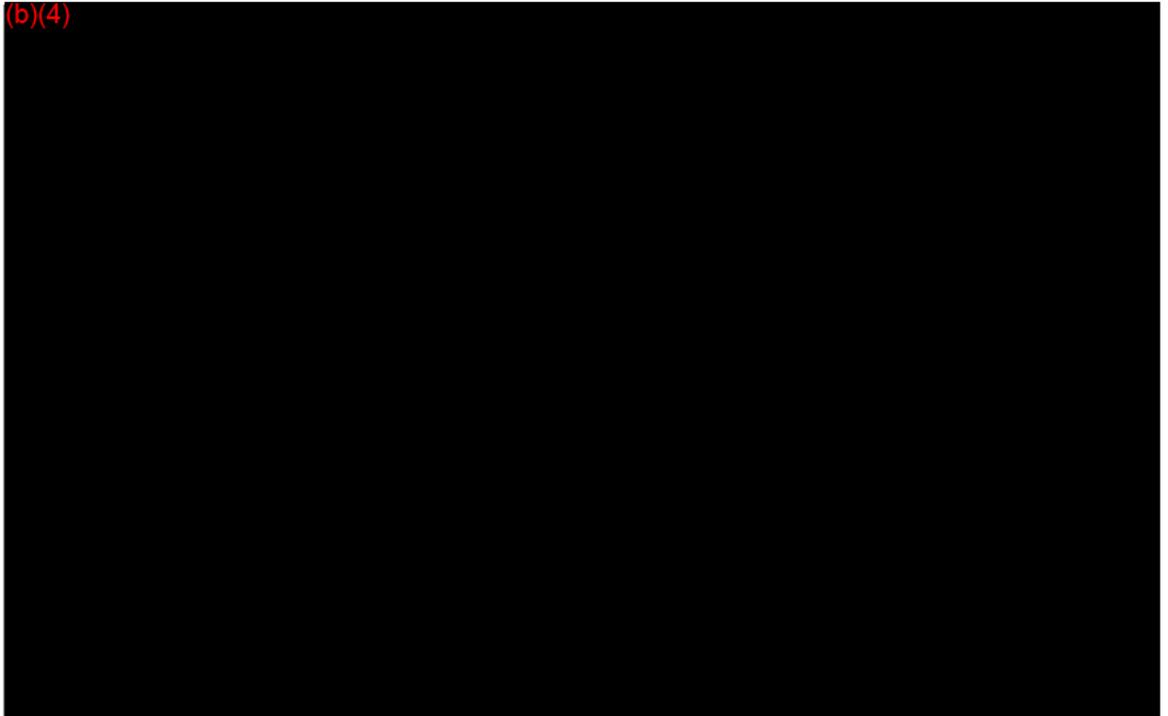
QTR --

(b)(4) Testing

Test Report of MediGuide™

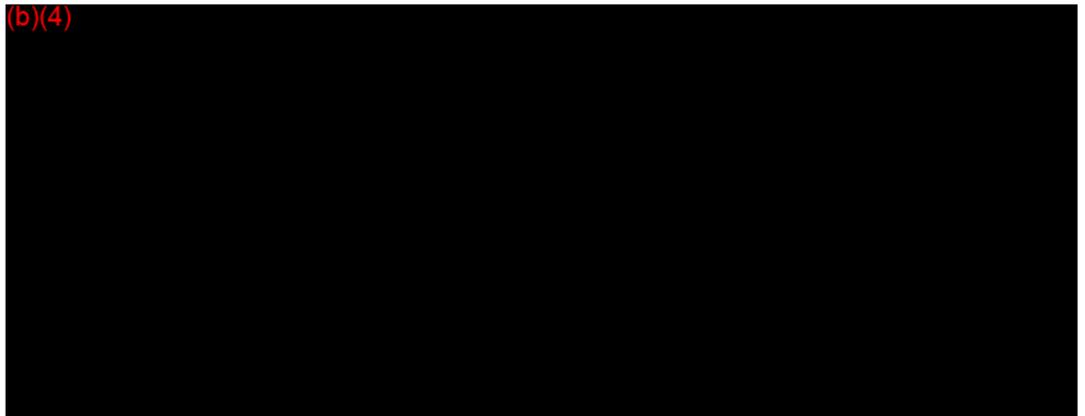
(b)(4) Testing

(b)(4)



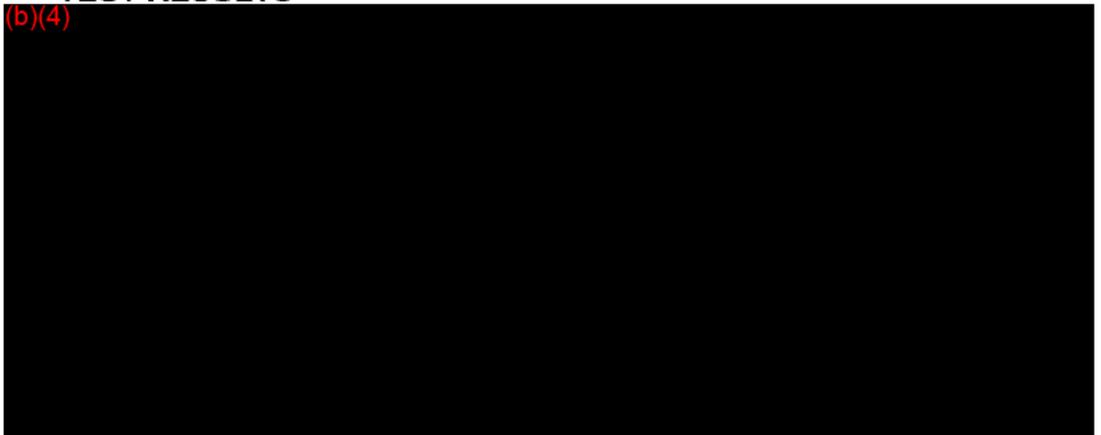
ACCEPTANCE CRITERIA

(b)(4)



TEST RESULTS

(b)(4)



10.2 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.3 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) Testing QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) Testing QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4) Testing

(b)(4)
Testing

QTR -

(b)(4) Testing

Test Report of MediGuide™

(b)(4) Testing

(b)(4)



ANALYSIS

(b)(4)

(b)(4)

10.5

(b)(4) Testing

TEST

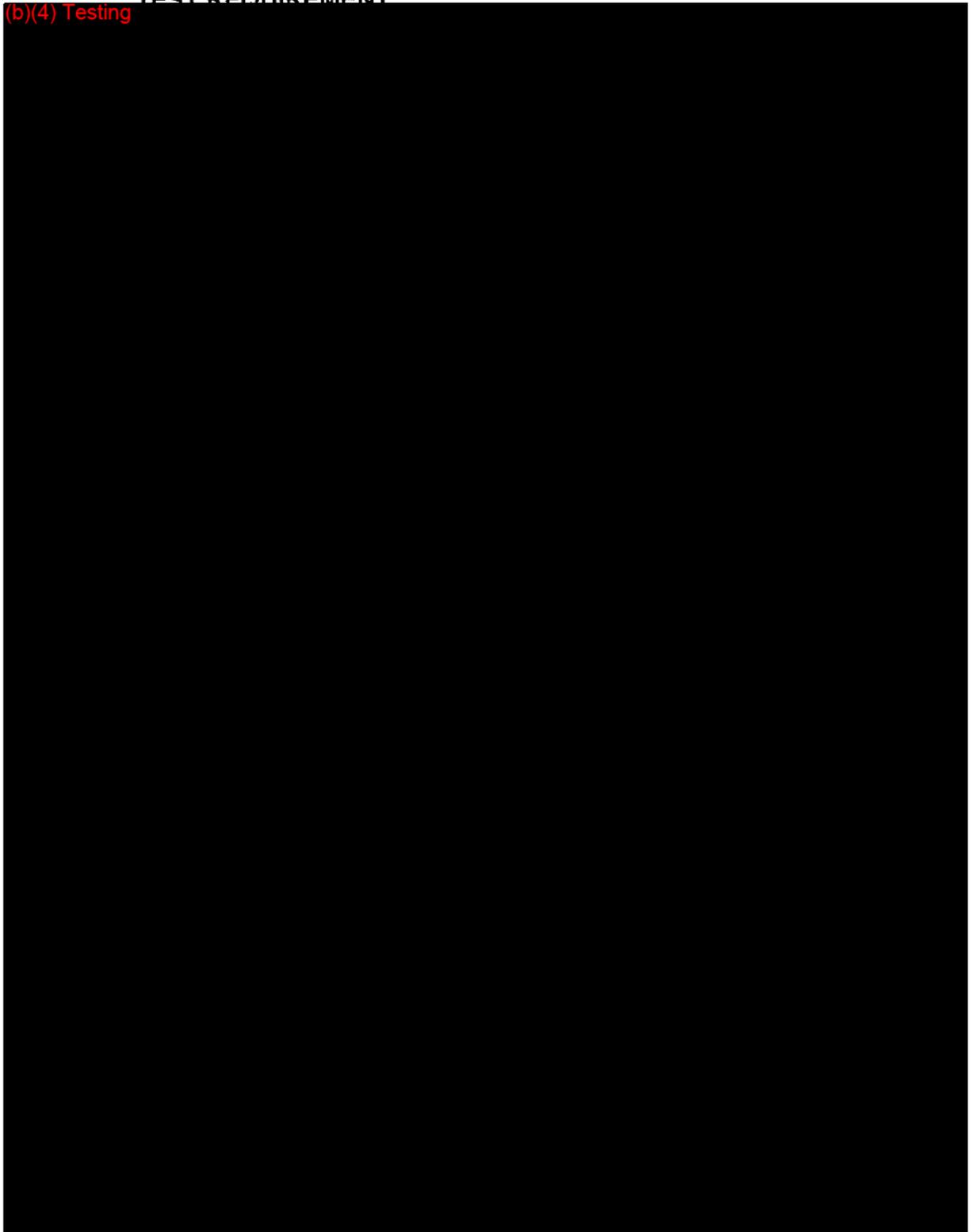
PURPOSE

(b)(4) Testing

(b)(4) Testing QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing



(b)(4) QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4) Testing

10.6

(b)(4) Testing TEST

PURPOSE

(b)(4) Testing

(b)(4)

QTR (b)(4) Testing

Test Report of MediGuide™ (b)(4) Testing

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4) Testing

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

(b)(4) Testing

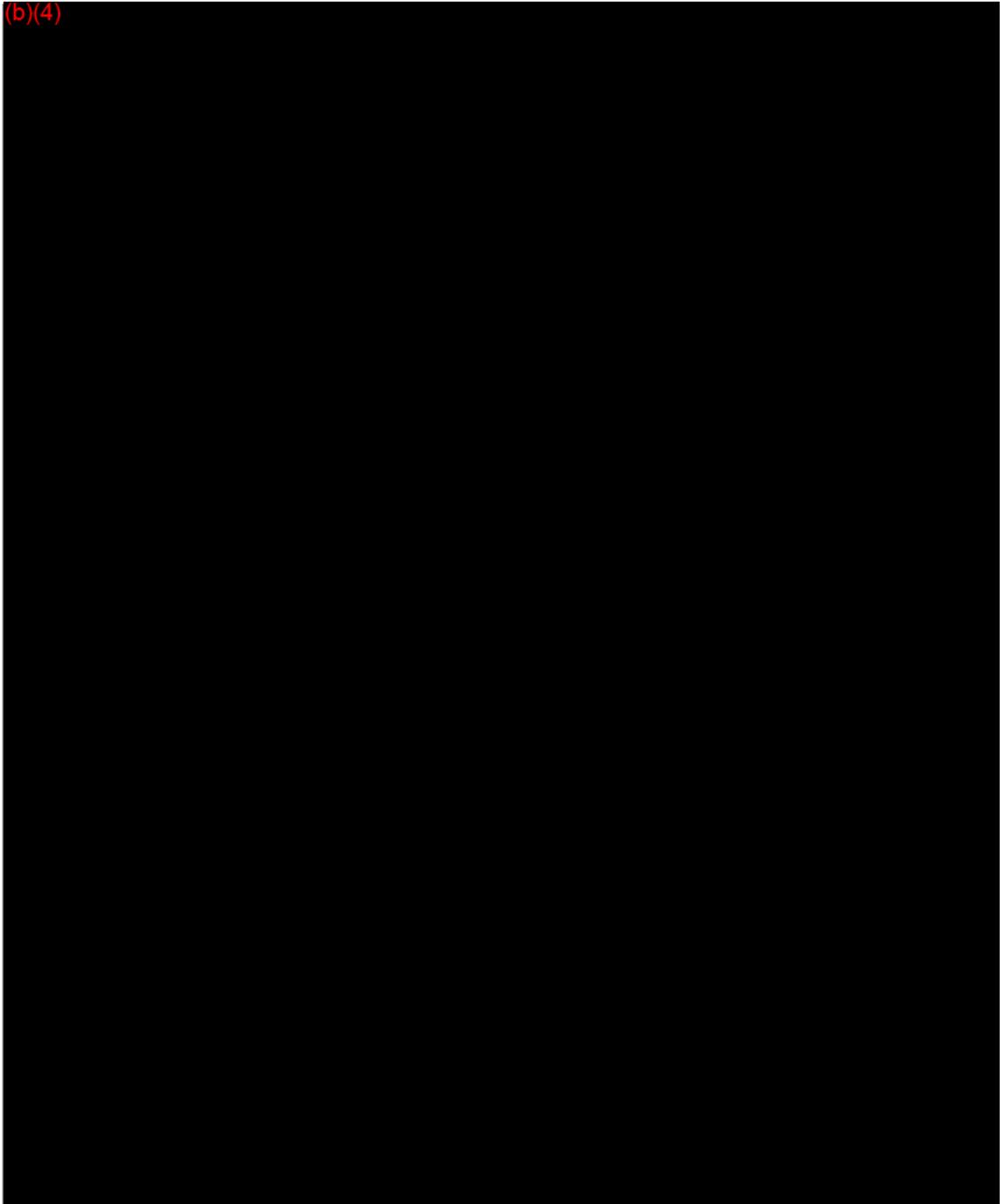
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(b)(4) Testing

Test Report of MediGuide

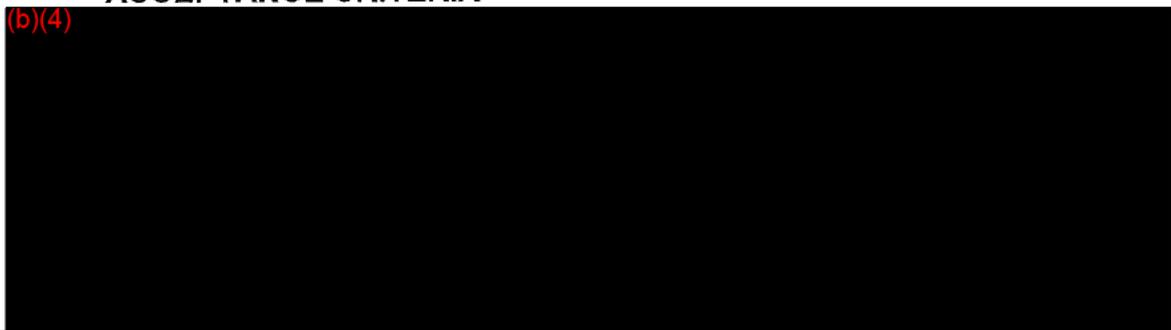
(b)(4) Testing

(b)(4)

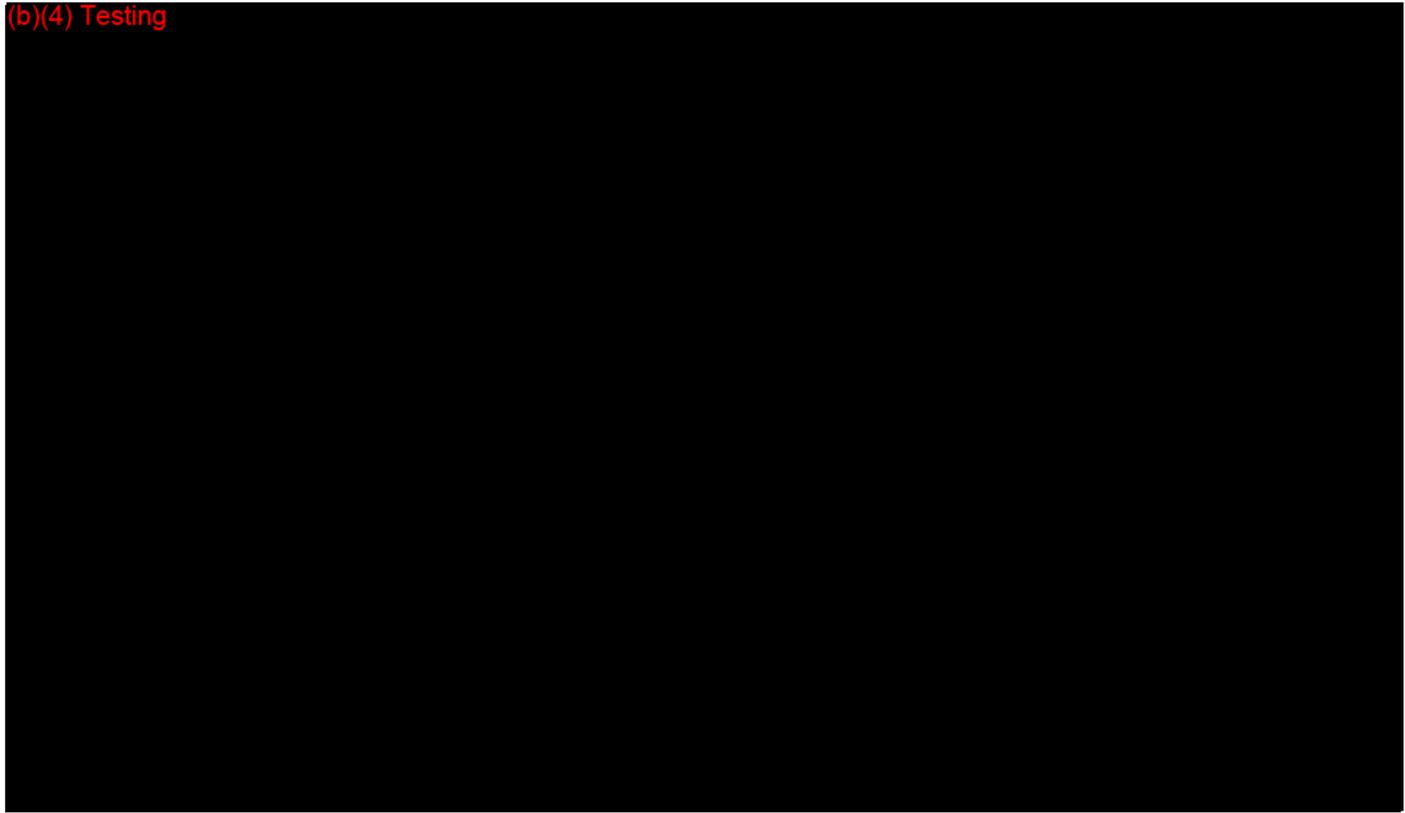


ACCEPTANCE CRITERIA

(b)(4)

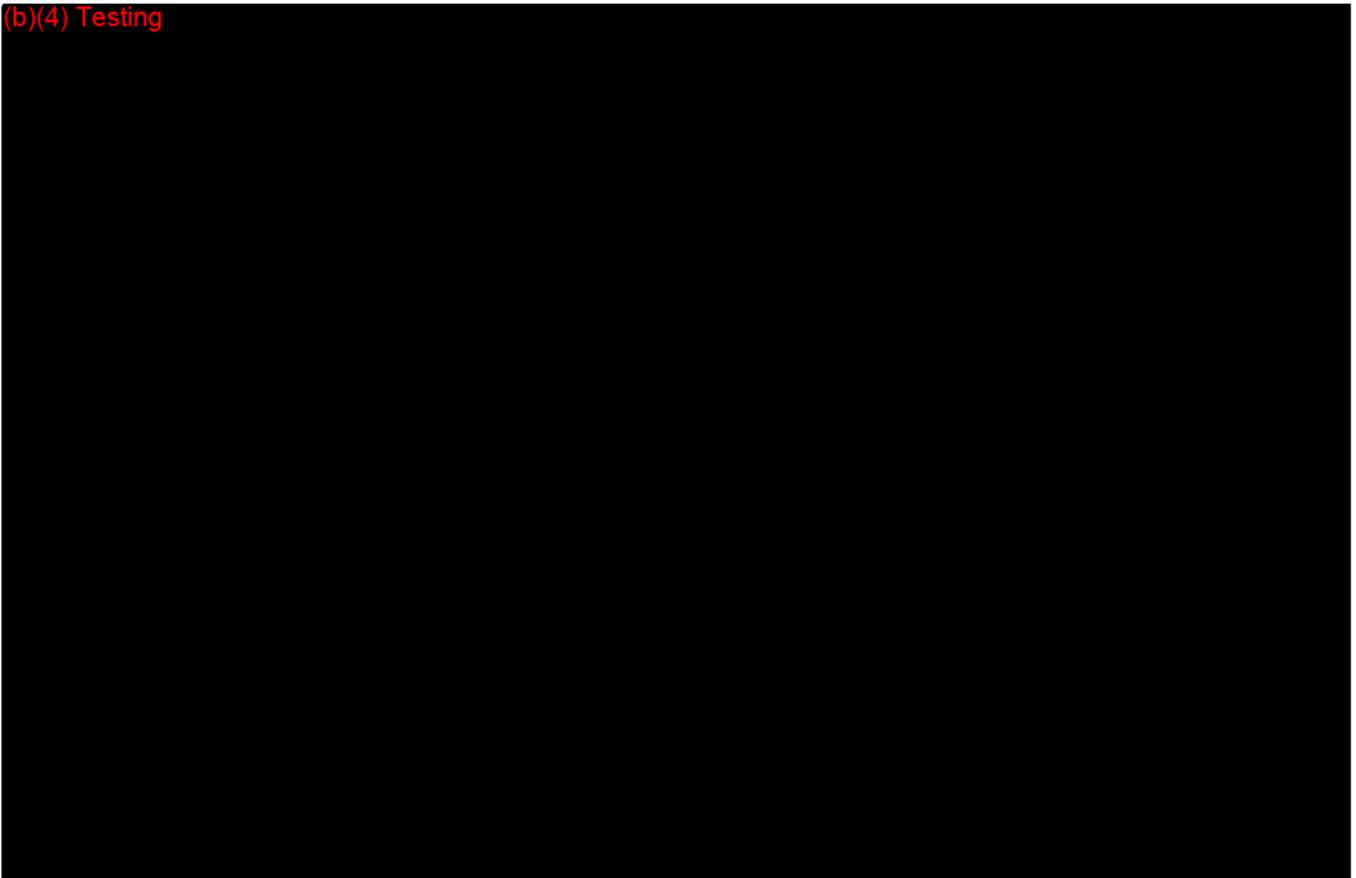


(b)(4) Testing



TEST RESULTS

(b)(4) Testing



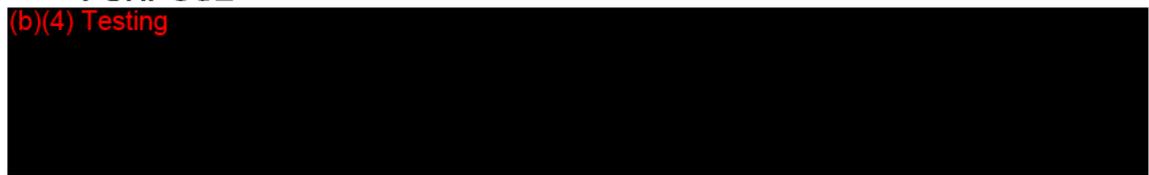
(b)(4) Testing



10.8 (b)(4) Testing TEST

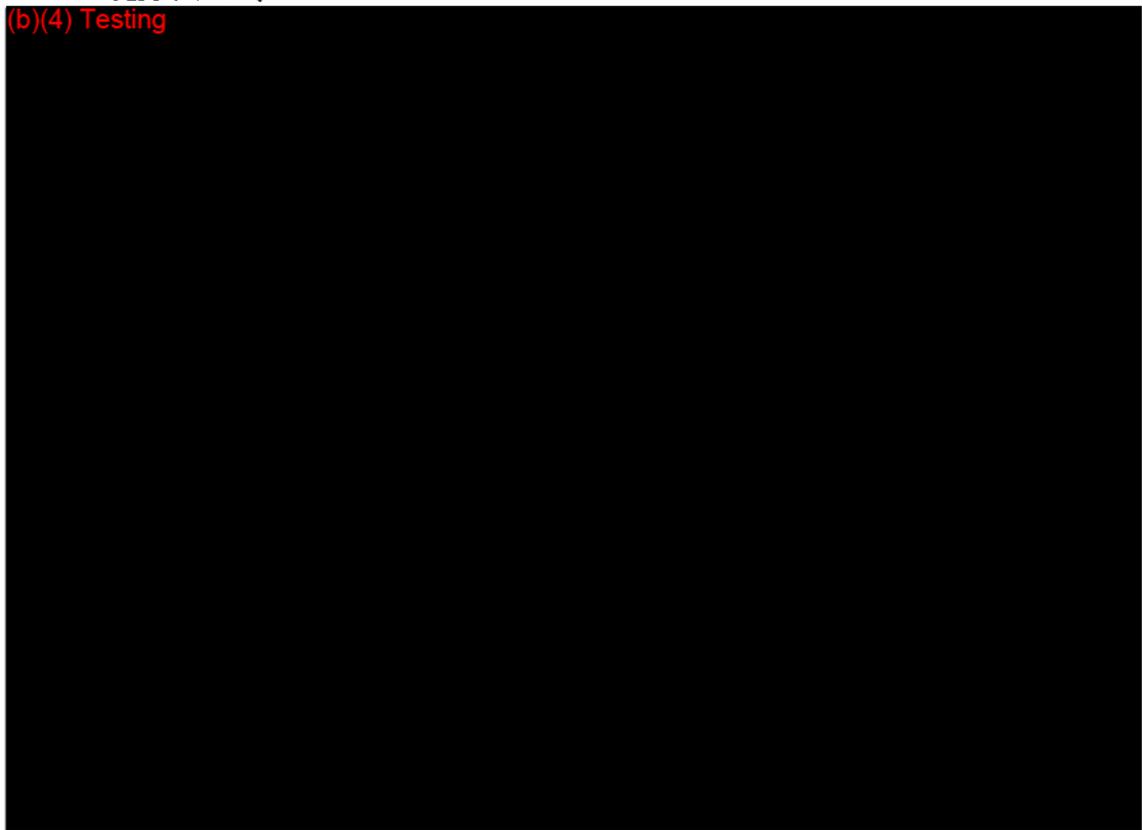
PURPOSE

(b)(4) Testing



TEST REQUIREMENT

(b)(4) Testing



(b)(4) Testing

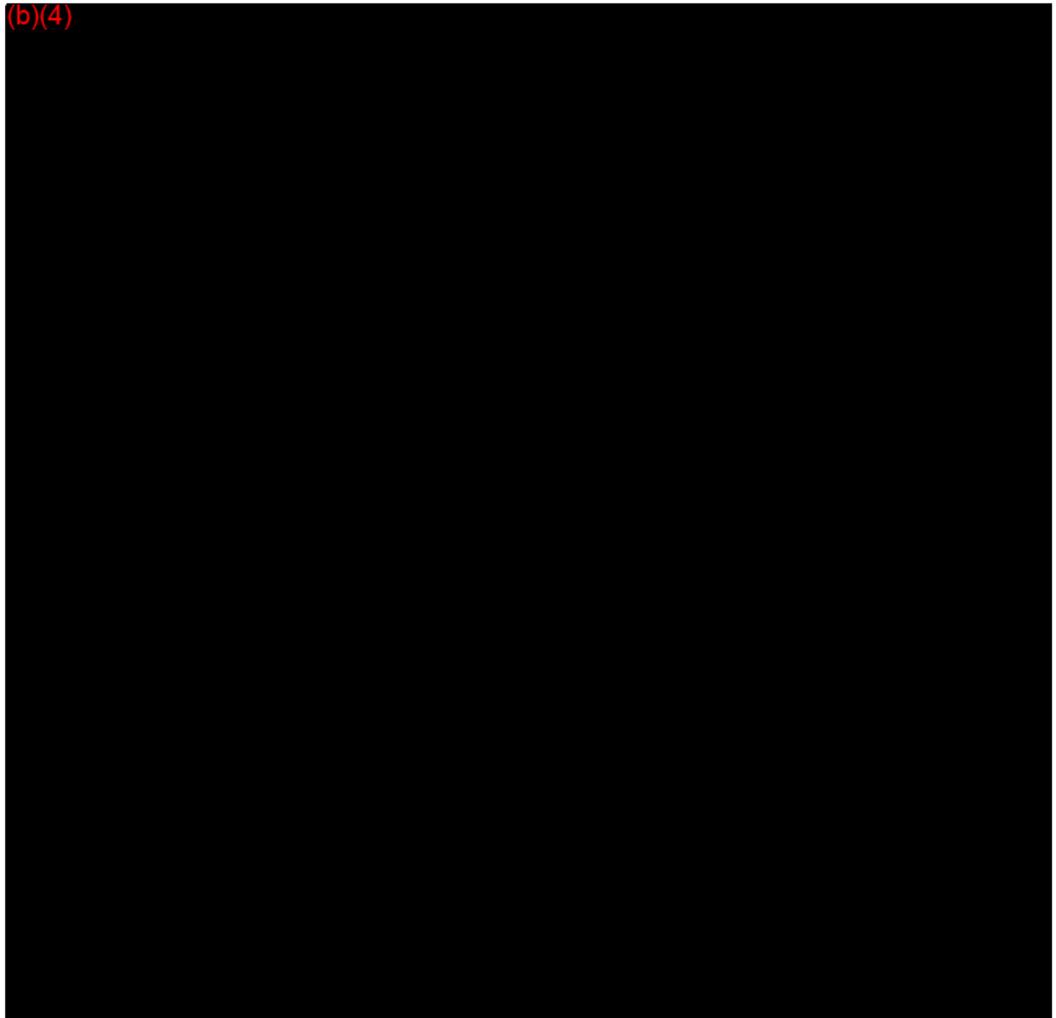
QTR

(b)(4) Testing

Test Report of MediGuide™

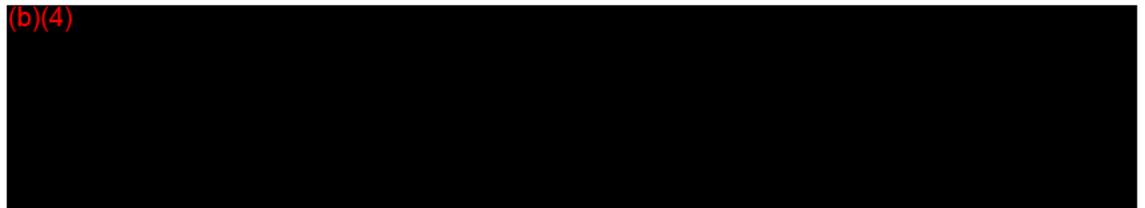
(b)(4) Testing

(b)(4)



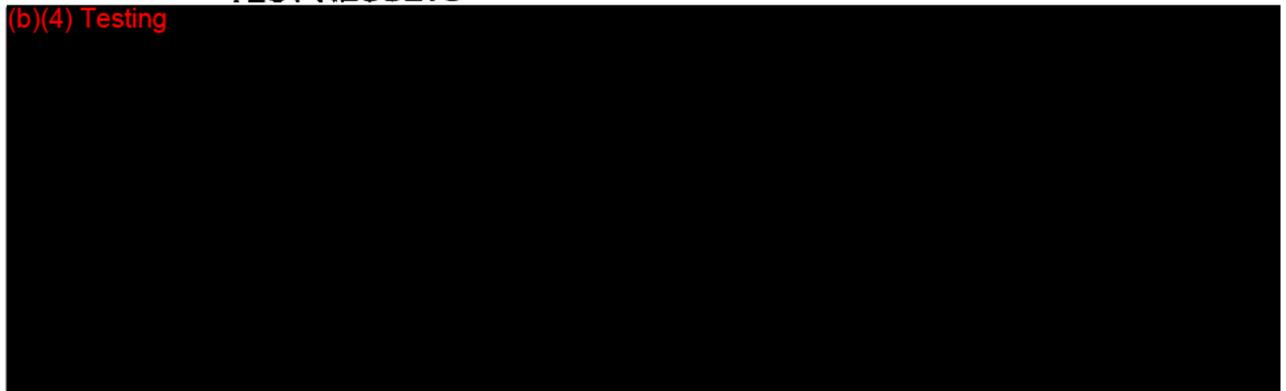
ACCEPTANCE CRITERIA

(b)(4)



TEST RESULTS

(b)(4) Testing



(b)(4)
Testing

QTR -

(b)(4) Testing

Test Report of MediGuide™

(b)(4) Testing

(b)(4) Testing

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

TEST RESULTS

(b)(4) Testing



ST. JUDE MEDICAL
MEDICAL EQUIPMENT

Company Confidential

21(25)

Design Assurance

(b)(4) Testing

ANALYSIS

(b)(4) Testing

(b)(4) Testing QTR - (b)(4) Testing Test Report of MediGuide™ (b)(4) Testing

(b)(4) Testing

PURPOSE

(b)(4) Testing

TEST REQUIREMENT

(b)(4) Testing

(b)(4)
Testing

QTR --

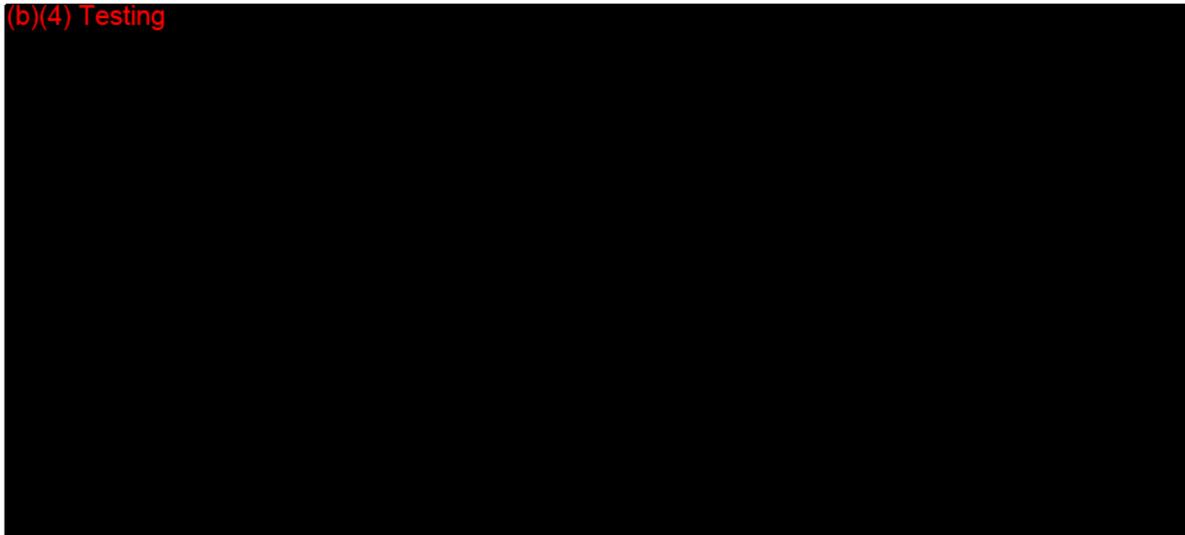
(b)(4) Testing

(b)
(4)

Test Report of MediGuide™

(b)(4) Testing

(b)(4) Testing



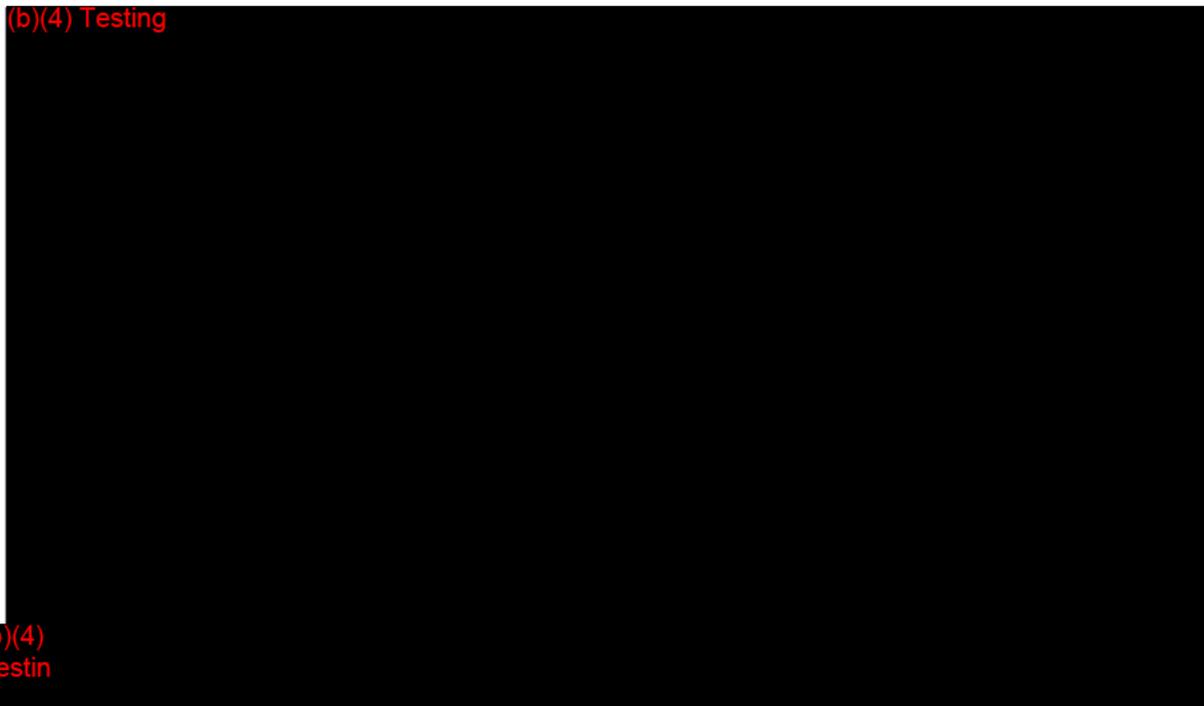
ACCEPTANCE CRITERIA

(b)(4) Testing



TEST RESULTS

(b)(4) Testing



(b)(4)
Testin
g

PURPOSE

(b)(4) Testing

(b)(4) Testing

QTR -

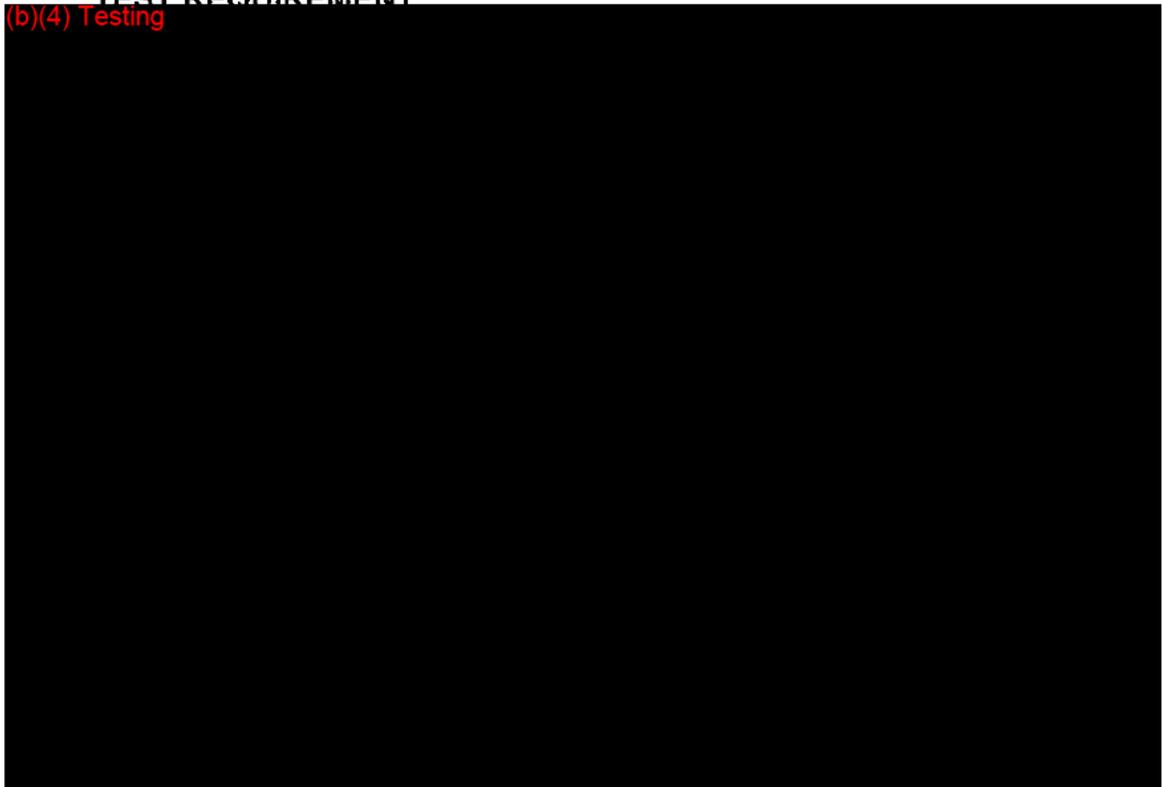
(b)(4) Testing

Test Report of MediGuide™

(b)(4) Testing

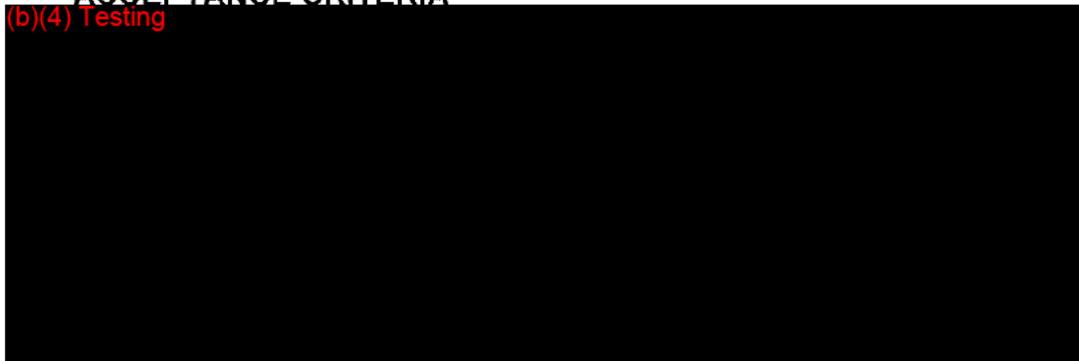
TEST REQUIREMENT

(b)(4) Testing



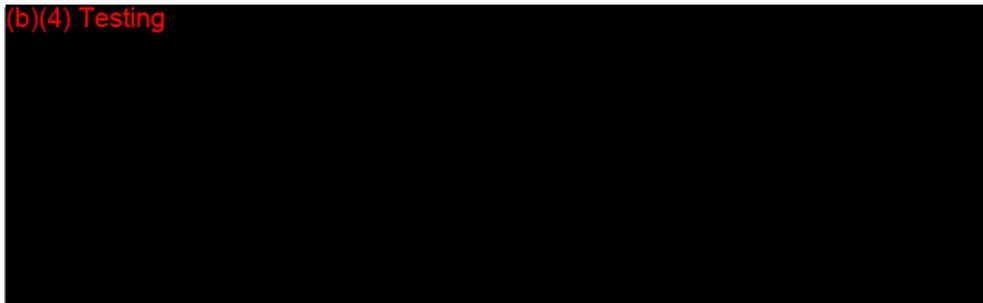
ACCEPTANCE CRITERIA

(b)(4) Testing



TEST RESULTS

(b)(4) Testing



Appendix 11

(b)(4) Testing QTR - (b)(4) Testing Test of MediGuide™ (b)(4) Testing

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: January 09, 2012
		Page 1(21)
Document Number: (b)(4) Testing	Revision: (b)(4) Tes	
Document Title: QTR - (b)(4) Testing Test of MediGuide™ (b)(4) Testing		
Model number: DS2M032		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6)	(b)(6)	(b)(6) 1/25/12
Design Assurance		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)	<i>CCanan</i>	16-JAN-2012
Approved by/Title:		
(b)(6)	<i>See Attached</i>	
Regulatory Affairs (OUS)		
Approved By/Title:		
(b)(6)	<i>See Attached</i>	
Development		
Approved By/Title:		
(b)(6)	<i>See Attached</i>	
Program/Development Management		
Approved By/Title:	(b)(6)	1/24/12
(b)(6)		
Design Assurance Management		

(b)(4) Testing QTR - (b)(4) Testing Test of MediGuide™ (b)(4) Testing

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: January 09, 2012	
		Page 1(21)	
Document Number: (b)(4) Testing		Revision: (b)(4) (4) (4)	
Document Title: QTR - (b)(4) Testing Test of MediGuide™ Guidewire (b)(4)			
Model number: DS2M032			
1.0 CONCURRENCE			
Author Name/Title:	Signature:	Date:	
(b)(6) Design Assurance			
Approved by/Title:			
Colleen Canan Regulatory Affairs (US)			
Approved by/Title:	(b)(6)	1/26/12	
(b)(6) Regulatory Affairs (OUS)			
Approved By/Title:			
(b)(6) Development			
Approved By/Title:			
(b)(6) Program/Development Management			
Approved By/Title:			
(b)(6) Design Assurance Management			

(b)(4) Testing QTR - (b)(4) Testing Test of MediGuide™ (b)(4) Testing

 ST. JUDE MEDICAL <small>More Control. Less Risk.</small>		Date: January 09, 2012
		Page 1(21)
Document Number: (b)(4) Testing	Revision: (b)(4)	
Document Title: QTR - (b)(4) Testing Test of MediGuide™ Guidewire Model number: DS2M032		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6)		
Design Assurance		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)		
Approved by/Title:		
(b)(6)		
Regulatory Affairs (OUS)	(b)(6)	
Approved By/Title:	(b)(6)	24 Jan 2012
(b)(6)	(b)(6)	
Development	(b)(6)	
Approved By/Title:	(b)(6)	
(b)(6)	(b)(6)	24 Jan 2012
Program/Development Management	(b)(6)	
Approved By/Title:	(b)(6)	
(b)(6)	(b)(6)	
Design Assurance Management	(b)(6)	

(b)(4) Testing QTR - (b)(4) Testing Test of MediGuide™ (b)(4) Testing

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(b)(4) QTR - (b)(4) Test of MediGuide™ (b)(4)

(b)(4) Date: January 9, 2012
QTR - (b)(4) Test of MediGuide™ Guidewire
(b)(4)
Model number: DS2M032

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

Table 2 references the tests included in this test report.

Table 2 Tests Included in this Test Report

Test #	Test	Requirement/ Specification
10.1	(b)(4)	(b)(4)
10.2	(b)(4)	(b)(4)
10.3	(b)(4)	(b)(4)
10.4	(b)(4)	(b)(4)
10.5	(b)(4)	(b)(4)
10.6	(b)(4)	(b)(4)
10.7	(b)(4)	(b)(4)
10.8	(b)(4)	(b)(4)

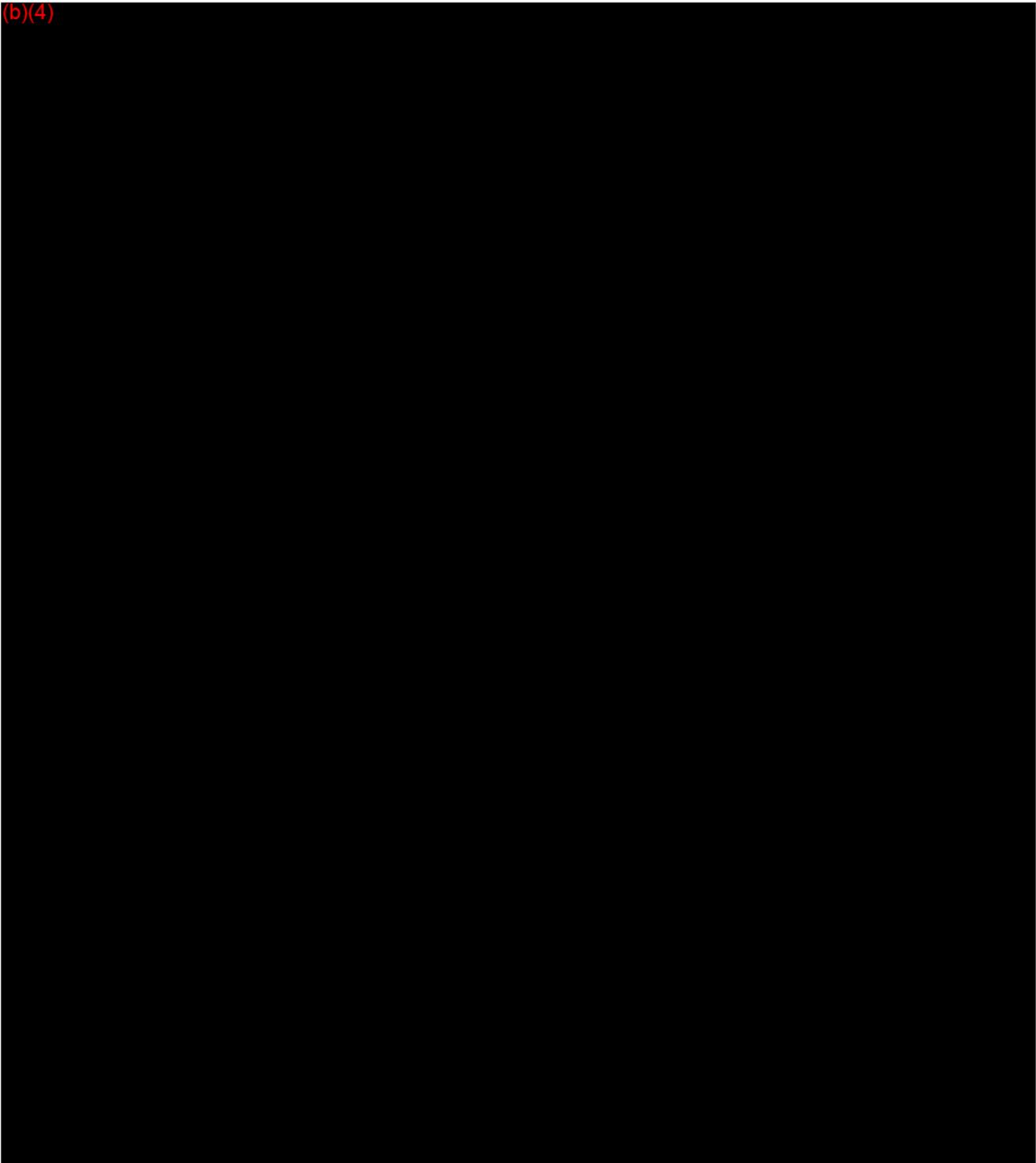
Table 3 Tests Excluded from this Report

Test	Requirement/ Specification	Rationale
(b)(4)	(b)(4)	(b)(4)

(b)(4) QTR - (b)(4) Test of MediGulde™ Guidewire (b)(4)

(b)(4) Study:

(b)(4)



4.1 SUMMARY OF RESULTS

All samples met the applicable requirements of (b)(4)

 ST. JUDE MEDICAL <small>MOST CONFIDENTIAL</small>	Company Confidential	5(21)	Design Assurance
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(b)(4)

QTR

(b)(4)

Test of MediGuide™ Guidewire

(b)(4)

4.2 CONCLUSIONS

(b)(4)

5.0 ASSOCIATED DOCUMENTS

	Document #	Rev #*	Document Title
5.1	(b)(4)		
5.2			
5.3			
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			
5.10			
5.11			
5.12			
5.13			
5.14			
5.15			

(b)(4) QTR - (b)(4) Test of MediGuide™ Guidewire (b)(4)

	Document #	Rev #*	Document Title
	(b)(4)		
5.16			
5.17			
5.18			
5.19			

* Testing was completed with the most current revision.

(b)(4)

6.0 ASSOCIATED TEST EQUIPMENT

Table 4 Associated Test Equipment

	Description	Applicable Tests
6.1	(b)(4)	
6.2		
6.3		
6.4		
6.5		
6.6		

Where applicable, equipment was calibrated and traceable to the National Institute of Standards and Technology (NIST) prior to the initiation of tests.

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

Description	ID	(b)(4)
MediGuide Guidewire (b)(4)	Model # DS2M032	(b)(4)

(b)(4)

8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)

(b)(4) QTR - (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

9.0 TEST SEQUENCE

MediGuide Guidewire (b)(4)
(b)(4)

TEST FLOW

DS2M032 – MediGuide Guidewire (b)(4)
(b)(4)

(b)(4) QTR (b)(4) Test of MediGuide™ Guidewire (b)(4)

10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4) QTR (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

TEST RESULTS

(b)(4)

10.2 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.3 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

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

(b)(4) QTR - (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

10.4 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR (b)(4) Test of MediGuide™ Guidewire (b)(4)

10.5 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR - (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4) QTR (b)(4) Test of MediGuide™ Guidewire (b)(4)

Test	(b)(4)
5	(b)(4)
6	(b)(4)
7	(b)(4)
8	(b)(4)
9	(b)(4)
10	(b)(4)

* Acceptance criteria table clarified from (b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR - (b)(4) Aging) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

10.6 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR - (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

10.7 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR - (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR (b)(4) Test of MediGuide™ Guidewire (b)(4)

(b)(4)

10.8 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4)

QTR -

(b)(4)

Test of MediGuide™ Guidewire

(b)(4)

(b)(4)



Appendix 12

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: January 7, 2012
		Page 1(19)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4) Model number: DS2M030		
1.0 CONCURRENCE		
Author Name/Title: (b)(6) Design Assurance Engineer	Signature: (b)(6)	Date: (b)(6) 1/24 ⁵ /12 1/25/12
Approved by/Title: Colleen Canan Regulatory Affairs (US)	See Attached	
Approved by/Title: (b)(6) Regulatory Affairs (OUS)	See Attached	
Approved By/Title: (b)(6) Principal Development Engineer	24 Jan 2012	
Approved By/Title: (b)(6) Program/Development Management	24 Jan 2012	
Approved By/Title: (b)(6) Manager, QA Operations	See Attached	

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: January 7, 2012
		Page 1(19)
Document Number: (b)(4)	Revision: (b)(4)	
Document Title: QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4) Model number: DS2M030		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6) Design Assurance Engineer		
Approved by/Title:		24 JAN 2012
Colleen Canan Regulatory Affairs (US)		
Approved by/Title:		
(b)(6) Regulatory Affairs (OUS)		
Approved By/Title:		
(b)(6) Principal Development Engineer		
Approved By/Title:		
(b)(6) Program/Development Management		
Approved By/Title:	(b)(6)	1/24/12
(b)(6) Manager, QA Operations		

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: January 7, 2012
		Page 1(19)
Document Number (b)(4)	Revision: (b)(4)	
Document Title: QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4) Model number: DS2M030		
1.0 CONCURRENCE		
Author Name/Title:	Signature:	Date:
(b)(6) Design Assurance Engineer		
Approved by/Title:		
Colleen Canan Regulatory Affairs (US)		
Approved by/Title:	(b)(6)	1/24/12
(b)(6) Regulatory Affairs (OUS)		
Approved By/Title:		
(b)(6) Principal Development Engineer		
Approved By/Title:		
(b)(6) Program/Development Management		
Approved By/Title:		
(b)(6) Manager, QA Operations		

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(b)(4) Date: January 7, 2012
QTR - (b)(4) Test Report of MediGuide
Guidewire (b)(4)
Model number: DS2M030

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

Table 2 references the tests included in this test report.

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

Table 2 Tests Included in this Test Report

Test #	Test	Requirement/ Specification
10.1	(b)(4)	
10.2		
10.3		
10.4		
10.5		
10.6		
10.7		
10.8		
10.9		

(b)(4)

(b)(4)

QTR - (b)(4)

Test Report of MediGuide Guidewire (b)(4)

(b)(4)

4.1 SUMMARY OF RESULTS

(b)(4)

4.2 CONCLUSIONS

(b)(4)

5.0 ASSOCIATED DOCUMENTS

Table 3 Associated Documents

	Document #	Rev #*	Document Title
5.1	(b)(4)		
5.2			

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

	Document #	Rev #*	Document Title
5.3	(b)(4)		
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			
5.10			
5.11			
5.12			
5.13			
5.14			
5.15			

* Testing was completed with the most current revision.

(b)(4) Documents

6.0 ASSOCIATED TEST EQUIPMENT

Table 4 Associated Test Equipment

	Description	Applicable Tests
6.1	(b)(4)	
6.2		
6.3		
6.4		

Where applicable, equipment was calibrated and traceable to the National Institute of Standards and Technology (NIST) prior to the initiation of tests.

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4)

8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

9.0 TEST SEQUENCE

MediGuide Guidewire (b)(4)

(b)(4)

TEST FLOW 1

(b)(4)

10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

TEST RESULTS

(b)(4)

10.2 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

10.3 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR (b)(4) Test Report of MediGuide Guidewire (b)(4)

10.4 (b)(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

ANALYSIS

(b)(4)

(b)(4)

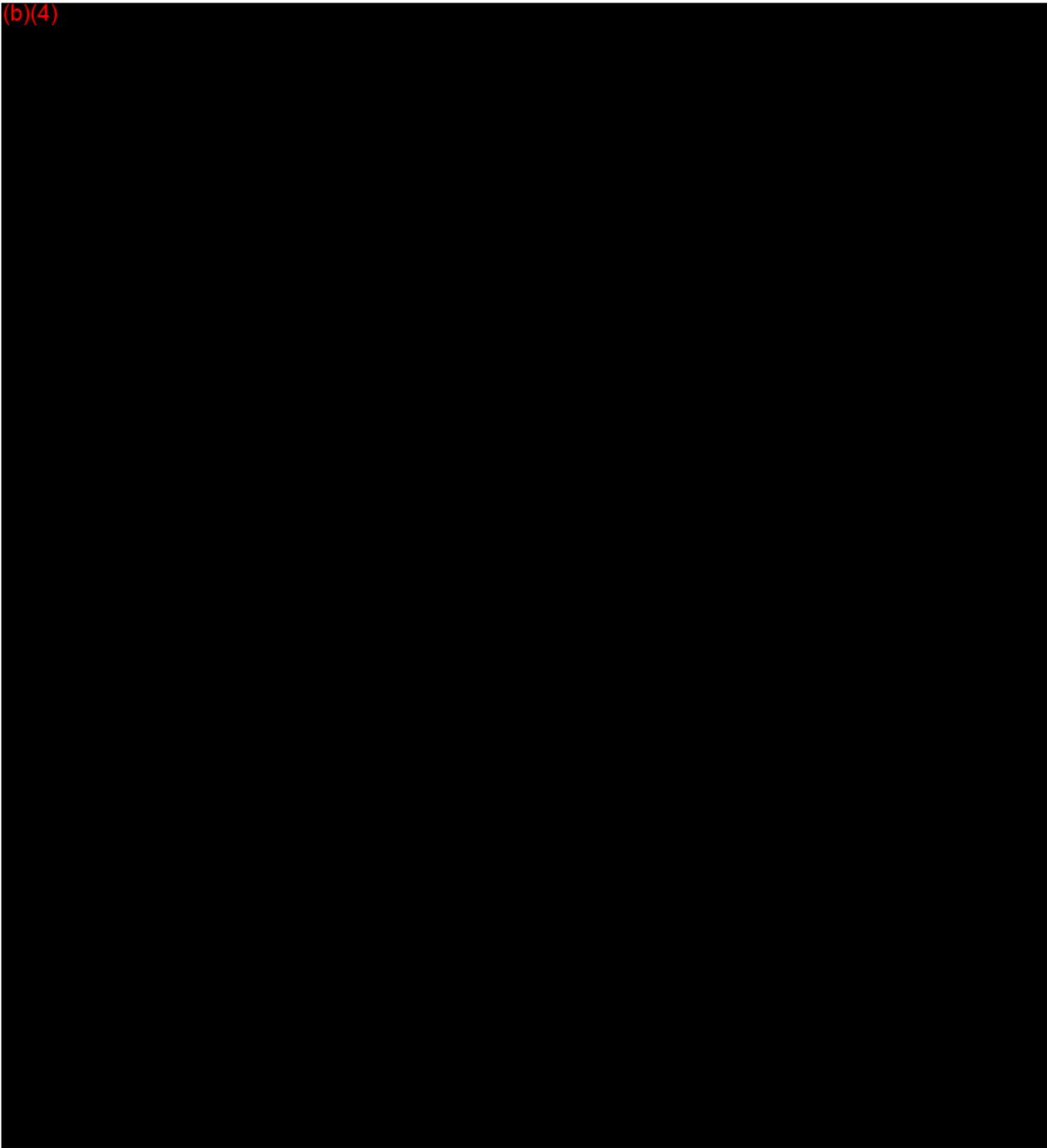
QTR-

(b)(4)

Test Report of MediGuide Guidewire

(b)(4)

(b)(4)



(b)(4)

(b)(4)

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

10.5 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR (b)(4) Test Report of MediGuide Guidewire (b)(4)

10.6 (b) (4) TEST
(4)

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR (b)(4) Test Report of MediGuide Guidewire (b)(4)

(b)(4)

10.7 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

(b)(4) QTR (b)(4) Test Report of MediGuide Guidewire (b)(4)

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

(b)(4) QTR - (b)(4) Test Report of MediGuide Guidewire (b)(4)

(b)(4)

10.8 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

10.9 (b)(4) TEST

PURPOSE

(b)(4)

TEST REQUIREMENT

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

Appendix 13

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: August 23, 2011	
		Page 1(19)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR – Biocompatibility Testing for MediGuide Guidewires Model numbers: DS2M027, DS2M028, DS2M029			
1.0 CONCURRENCE			
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(b)(4) QTR – Biocompatibility Testing for MediGuide Guidewires

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: August 23, 2011	
		Page 1(19)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR – Biocompatibility Testing for MediGuide Guidewires Model numbers: DS2M027, DS2M028, DS2M029			
1.0 CONCURRENCE			
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(b)(4) QTR - Biocompatibility Testing for MediGuide Guidewires

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: August 23, 2011	
		Page 1(19)	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR - Biocompatibility Testing for MediGuide Guidewires Model numbers: DS2M027, DS2M028, DS2M029			
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QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4)

Date: August 23, 2011

QTR – Biocompatibility Testing for MediGuide Guidewires

Model numbers: DS2M027, DS2M028, DS2M029

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

(b)(4) QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4)

The test sequence and tests performed are defined in Section 9.0.

TEST RATIONALE

(b)(4)

Table 2 Test Considerations per ISO (b)(4)

(b)(4) Test	Test performed	Rationale
(b)(4)		

¹ ISO (b)(4) evaluation of medical devices – Part 1 (Section (b)(4))

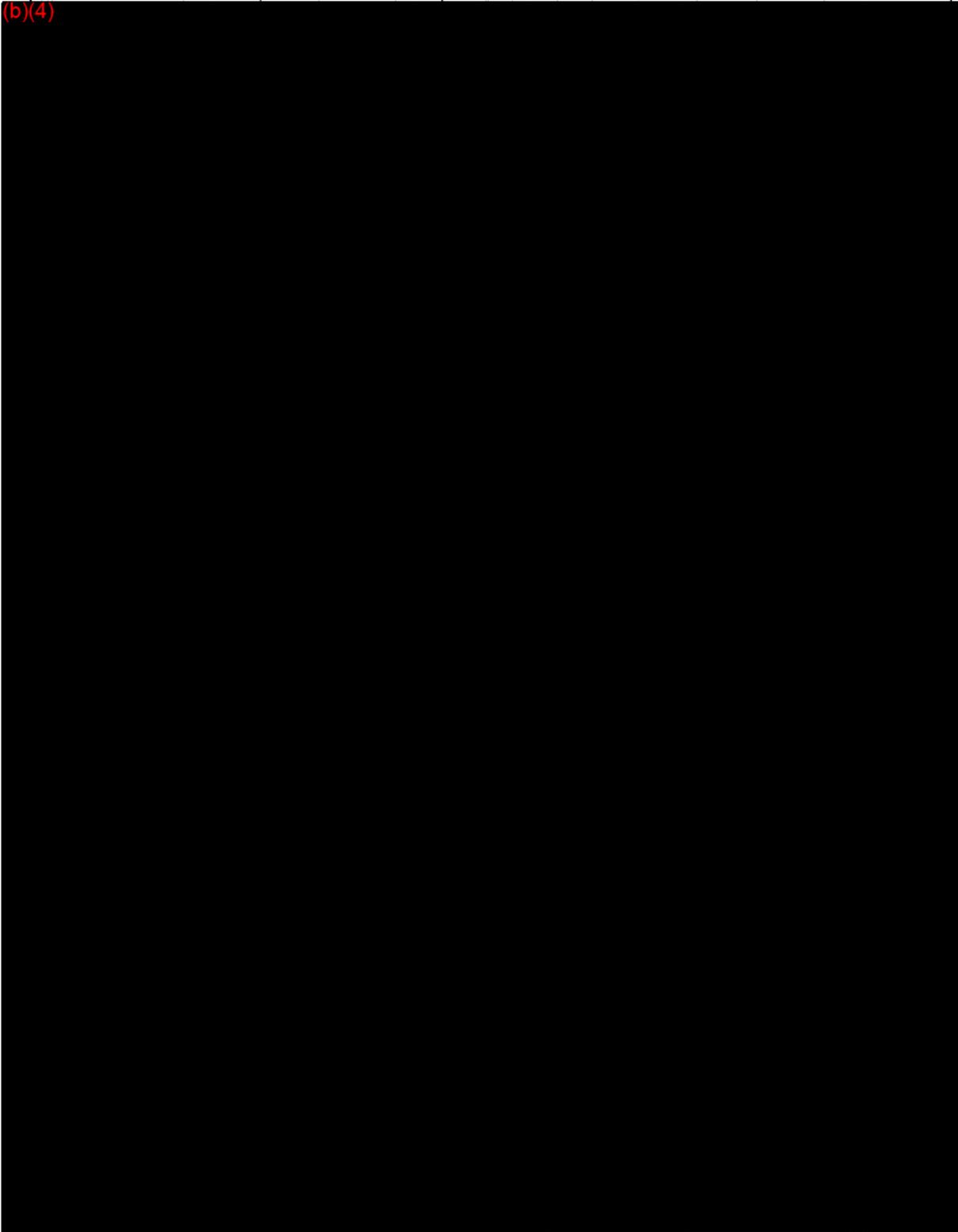
 ST. JUDE MEDICAL <small>ALMOST CONSTANT. LESS STOP.</small>	Company Confidential	4(19)	Design Assurance
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(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4) Test	Test performed	Rationale
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(b)(4)



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(b)(4) QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4)	Test	Test performed	Rationale
(b)(4)			

4.1 SUMMARY OF RESULTS

(b)(4)

4.2 CONCLUSIONS

(b)(4)

5.0 ASSOCIATED DOCUMENTS

Para	Document #	Rev #*	Document Title
5.1	(b)(4)		
5.2			
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5.5			
5.6			
5.7			
5.8			
5.9			

(b)(4) QTR – Biocompatibility Testing for MediGuide Guidewires

Para	Document #	Rev #*	Document Title
5.10	(b)(4)		
5.11			
5.12	United States Pharmacopeia		

* Testing was completed with the most current revision.

6.0 ASSOCIATED TEST EQUIPMENT

N/A.

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4)

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4)

8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)

Table 4 Sample Size Requirements

(b)(4)

(b)(4) QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4)

CPS Courier Medium Guidewire (b)(4)

9.0 TEST SEQUENCE

(b)(4)

10.0 TEST PROCEDURE

10.1 (b)(4)

Purpose

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

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(b)(4)

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QTR – Biocompatibility Testing for MediGuide Guidewires

10.2

(b)(4)

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(b)(4)

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10.3

(b)(4)

TEST

Purpose

(b)(4)

Methodology

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

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Acceptance Criteria

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Results

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TEST

Purpose

(b)(4)

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QTR – Biocompatibility Testing for MediGuide Guidewires

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10.5

(b)(4)

Purpose

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

Methodology

(b)(4)

Acceptance Criteria

(b)(4)

Results

(b)(4)

10.6 ASTM (b)(4)

Purpose

(b)(4)

Methodology

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

Acceptance Criteria

(b)(4)

Results

(b)(4)

10.7

(b)(4)

Purpose

(b)(4)

Methodology

(b)(4)

Acceptance Criteria

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4)

Results

(b)(4)

10.8

(b)(4)

Purpose

(b)(4)

Methodology

(b)(4)

Acceptance Criteria

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

(b)(4)

Results

(b)(4)

10.9

(b)(4)

Purpose

(b)(4)

Methodology

(b)(4)

Acceptance Criteria

(b)(4)

(b)(4)

QTR – Biocompatibility Testing for MediGuide Guidewires

Results

(b)(4)

10.10

(b)(4)

Purpose

(b)(4)

Methodology

(b)(4)

Acceptance Criteria

(b)(4)

Results

(b)(4)



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(b)(4)

Appendix 14

1.0 CONCURRENCE

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: October 4, 2011	
		Page 1 of 6	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: (b)(4) Testing for (b)(4) for the MediGuide Guidewires Model numbers: DS2M027, DS2M028, DS2M029			
Author Name/Title:	Dept:	Signature:	Date:
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(b)(4) (b)(4) Testing for (b)(4) for the MediGuide Guidewires

1.0 CONCURRENCE

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: October 4, 2011	
		Page 1 of 6	
Document Number: QTR 60038605		Revision: (b)(4)	
Document Title: (b)(4) Testing for (b)(4) for the MediGuide Guidewires			
Model numbers: DS2M027, DS2M028, DS2M029			
Author Name/Title:	Dept:	Signature:	Date:
(b)(6) Design Assurance Engineer	602		
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Approved by/Title:			
(b)(6) Regulatory Affairs (OUS)			
Approved By/Title:		(b)(6)	
(b)(6) Development Engineer	901014		06 Oct 2011
Approved By/Title:			
(b)(6) Engineering Group Leader, Development	901013		06 Oct 2011
Approved By/Title:			
(b)(6) Manager, Quality Assurance	602		
Approved By/Title:			
(b)(6) Staff Microbiologist	610		

(b)(4) (b)(4) Testing for (b)(4) for the MediGuide Guidewires

1.0 CONCURRENCE

 ST. JUDE MEDICAL <small>MODEL CONTROL DESIGN RISK</small>		Date: October 4, 2011	
		Page 1 of 6	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: (b)(4) Testing for (b)(4) for the MediGuide Guidewires Model numbers: DS2M027, DS2M028, DS2M029			
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(b)(4) (b)(4) testing for (b)(4) for the MediGuide Guidewires

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(b)(4) (b)(4) Testing for (b)(4) for the MediGuide Guidewires

(b)(4) Date: October 4, 2011
(b)(4) Testing for (b)(4) for the MediGuide
Guidewires
Model numbers: DS2M027, DS2M028, DS2M029

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

(b)(4) (b)(4) Testing for (b)(4) for the MediGuide Guidewires

Table 1 Models Covered By this Test Report

Stiffness	Model #	Part#
Extra-Firm	DS2M029	100053664
Medium	DS2M028	100053681
Soft	DS2M027	100053691

The test parameters and tests performed are defined in Section 10.0.

4.1 SUMMARY OF RESULTS

All samples passed the tests performed per QTP (b)(4)

4.2 CONCLUSIONS

(b)(4)

5.0 ASSOCIATED DOCUMENTS

Para	Document #	Rev # *	Document Title
5.1	(b)(4)		
5.2			
5.3			
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			
5.10			

* Testing was completed with the most current revision.

6.0 ASSOCIATED TEST EQUIPMENT

N/A

7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4)

(b)(4) (b)(4) Testing for (b)(4) for the MediGuide Guidewires

(b)(4)

8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)

9.0 TEST SEQUENCE

(b)(4)

10.0 TEST PROCEDURE

10.1 (b)(4)

PURPOSE

(b)(4)

(b)(4)

(b)(4)

Testing for

(b)(4)

for the MediGuide Guidewires

TEST METHODOLOGY

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

TEST RESULTS

(b)(4)

Appendix 15

 ST. JUDE MEDICAL MORE CONTROL. LESS RISK.	Date: August 24, 2011
	Page 1 of 10

Document Number: (b)(4)	Revision: (b)(4)
-------------------------	------------------

Document Title:
QTR - (b)(4) Testing for Biocompatibility for the Mediguide Guidewire
Model number: DS2M030

1.0 CONCURRENCE

Author Name/Title:	Dept:	Signature:	Date:
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Approved By/Title: (b)(6) Development Engineer		Please see attached sheet.	
Approved By/Title: (b)(6) Engineering Group Leader (Development)		Please see attached sheet.	
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Approved By/Title: (b)(6) Staff Microbiologist	610	(b)(6)	09/08/11

(b)(4) QTR (b)(4) Testing for Biocompatibility for the Mediguide Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: August 24, 2011	
		Page 1 of 11	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR - (b)(4) Testing for Biocompatibility for the Mediguide Guidewire (b)(4) Model number: DS2M030			
1.0 CONCURRENCE			
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(b)(4) QTR - (b)(4) Testing for Biocompatibility for the Mediguide Guidewire (b)(4)

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>		Date: August 24, 2011	
		Page 1 of 11	
Document Number: (b)(4)		Revision: (b)(4)	
Document Title: QTR - (b)(4) Testing for Biocompatibility for the Mediguide Guidewire Model number: DS2M030			
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(b)(4) QTR (b)(4) Testing for Biocompatibility for the Mediguide Guidewire (b)(4)

(b)(4) Date: August 24, 2011
QTR - (b)(4) Testing for Biocompatibility for the Mediguide Guidewire
(b)(4)
Model number: DS2M030

3.0 PURPOSE

(b)(4)

4.0 SCOPE

(b)(4)

(b)(4)

QTR -

(b)(4)

Testing for Biocompatibility for the Mediguide Guidewir

(b)(4)

(b)(4)



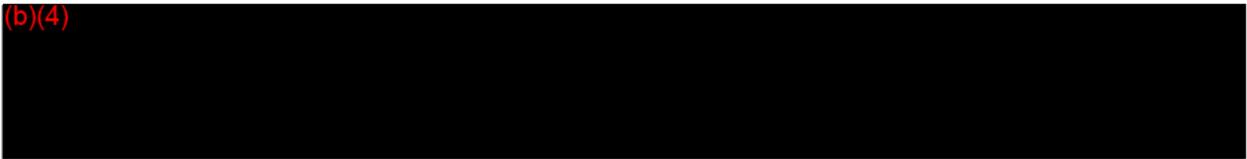
4.1 SUMMARY OF RESULTS

All samples passed the tests performed per QTP

(b)(4)

4.2 CONCLUSION

(b)(4)



5.0 ASSOCIATED DOCUMENTS

Para	Document #	Rev #*	Document Title
5.1	(b)(4)		
5.2			
5.3			
5.4			
5.5			
5.6			
5.7			
5.8			
5.9			
5.10			
5.11			
5.12			

Para	Document #	Rev #*	Document Title
			(b)(4)
5.13	(b)(4)		
5.14	United States Pharmacopeia		

* Testing will be completed with the most current revision.

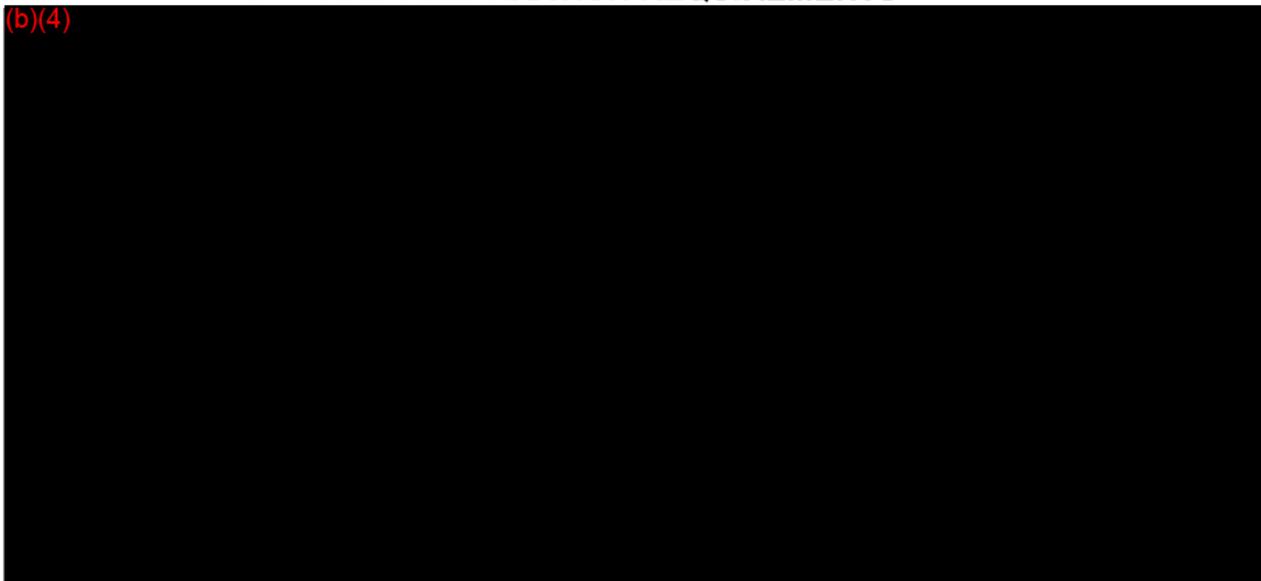
(b)(4) Documents

6.0 ASSOCIATED TEST EQUIPMENT

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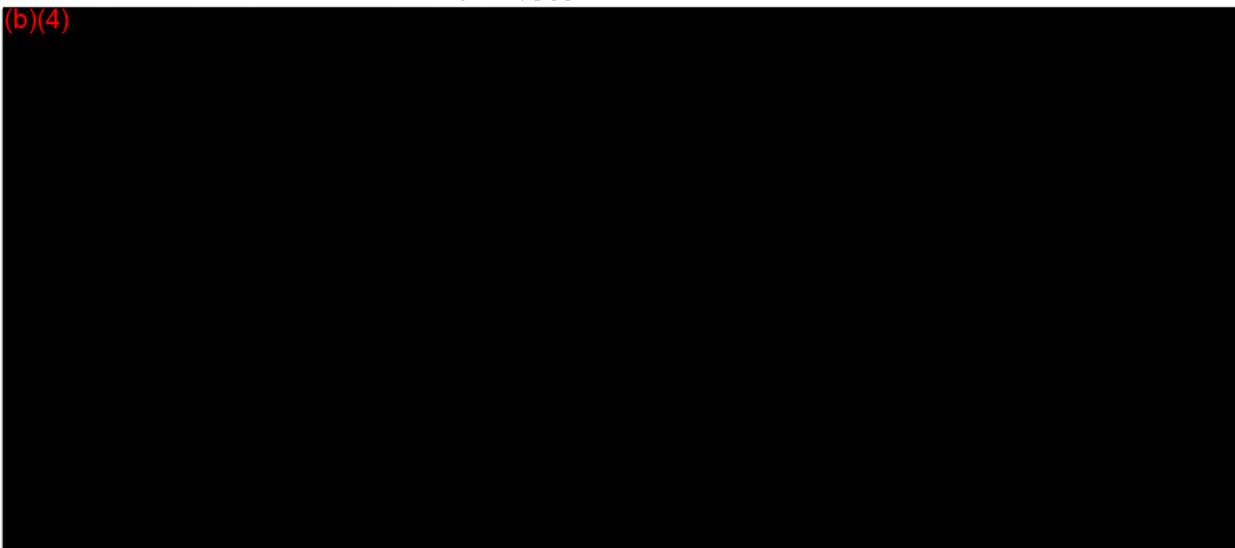
7.0 SAMPLE SIZE AND PREPARATION REQUIREMENTS

(b)(4)



8.0 SAMPLE SIZE JUSTIFICATION

(b)(4)



(b)(4)

9.0 TEST SEQUENCE

(b)(4)

10.0 BIOCOMPATIBILITY TESTING

10.1 (b)(4)

PURPOSE

(b)(4)

METHODOLOGY

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

(b)(4) [redacted]

RESULTS

(b)(4) [redacted]

10.2 (b)(4) [redacted] TEST

PURPOSE

(b)(4) [redacted]

METHODOLOGY

(b)(4) [redacted]

ACCEPTANCE CRITERIA

(b)(4) [redacted]

RESULTS

(b)(4) [redacted]

10.3 (b)(4) PYROGEN TEST

PURPOSE

(b)(4)

METHODOLOGY

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

RESULTS

(b)(4)

(b)(4) QTR (b)(4) Testing for Biocompatibility for the Mediguide Guidewire (b)(4)

(b)(4)

10.4 (b)(4) ASSAY – (b)(4) METHOD

PURPOSE

(b)(4)

METHODOLOGY

(b)(4)

ACCEPTANCE CRITERIA

(b)(4)

RESULTS

(b)(4)

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Appendix 17

(b)(4) Rev



Document Number	Revision	Status	ECO No.
(b)(4)	(b)	Production	(b)(4)

MediGuide (b)(4) **Drawing**

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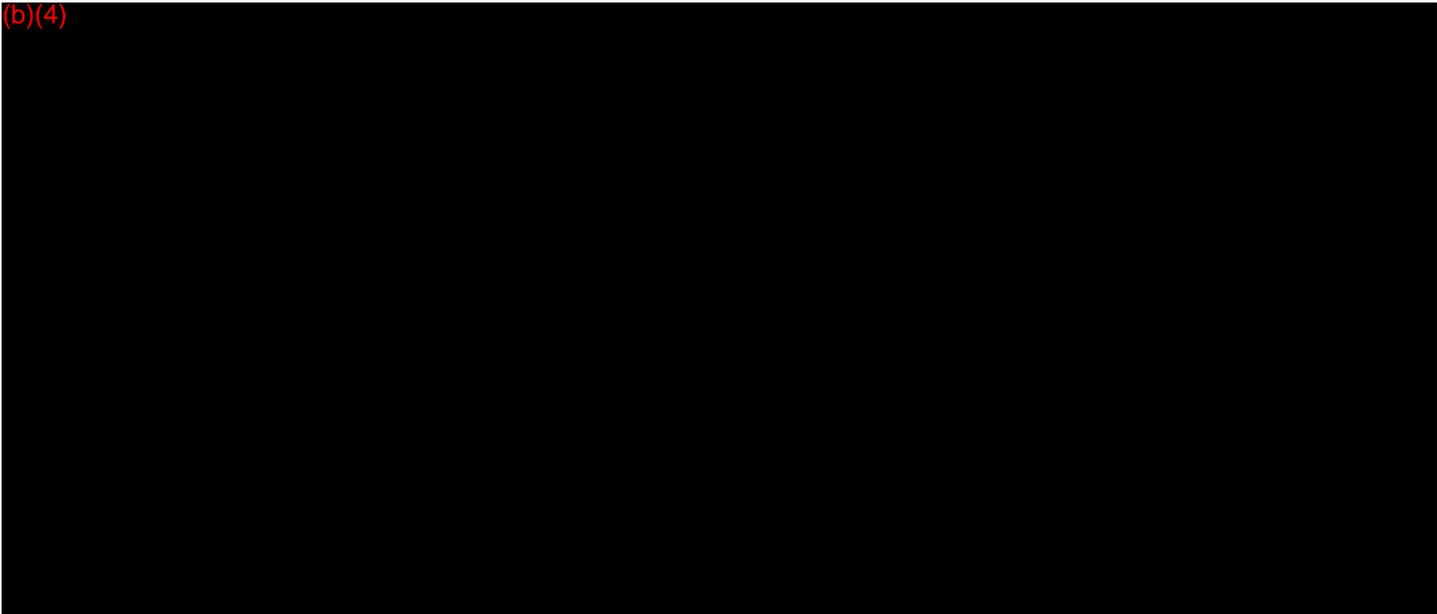
1.0 PURPOSE

(b)(4)



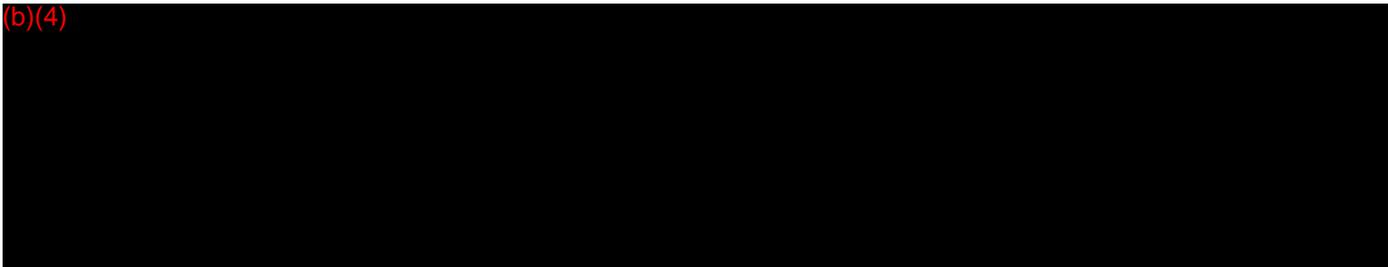
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(b)(4)



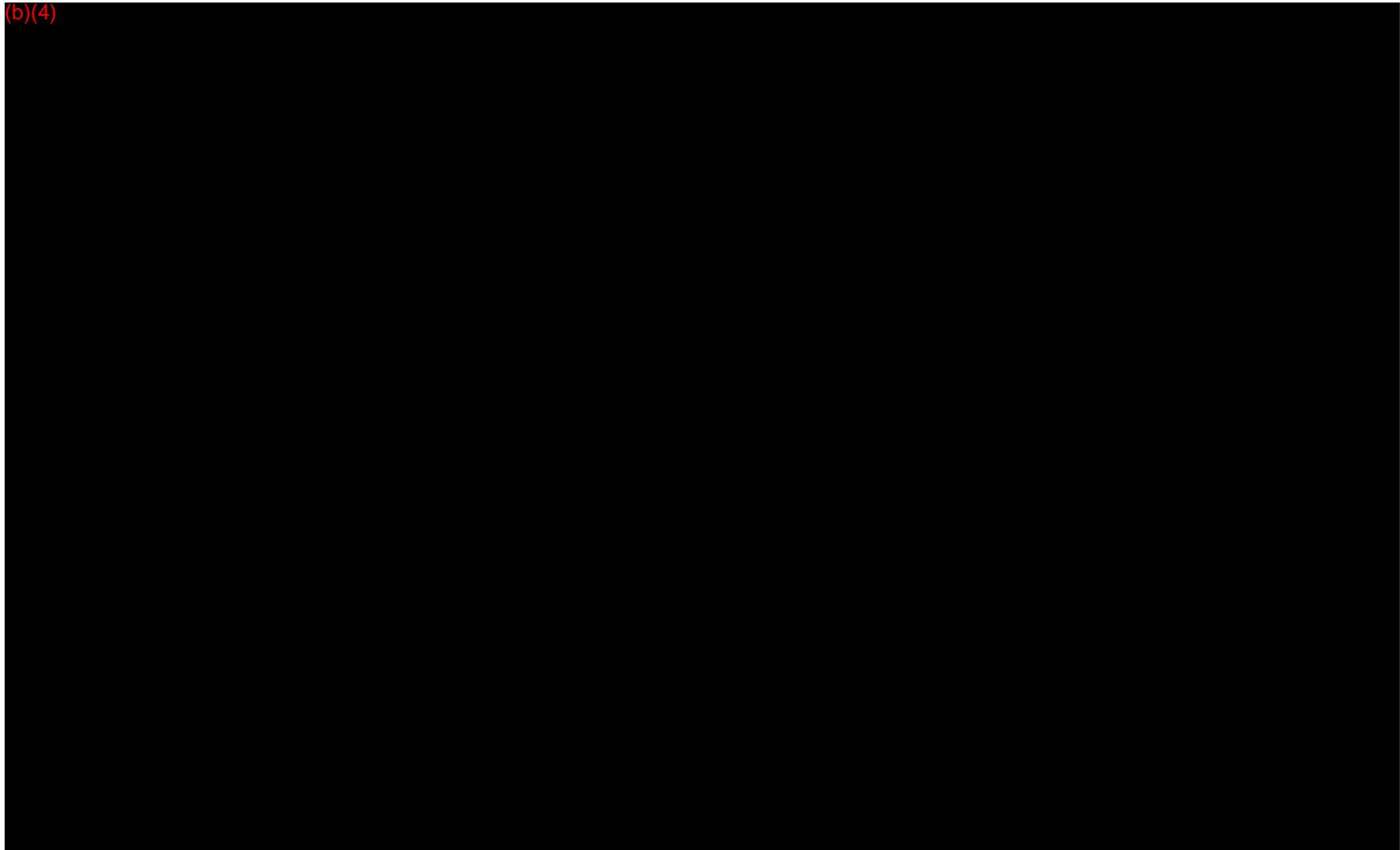
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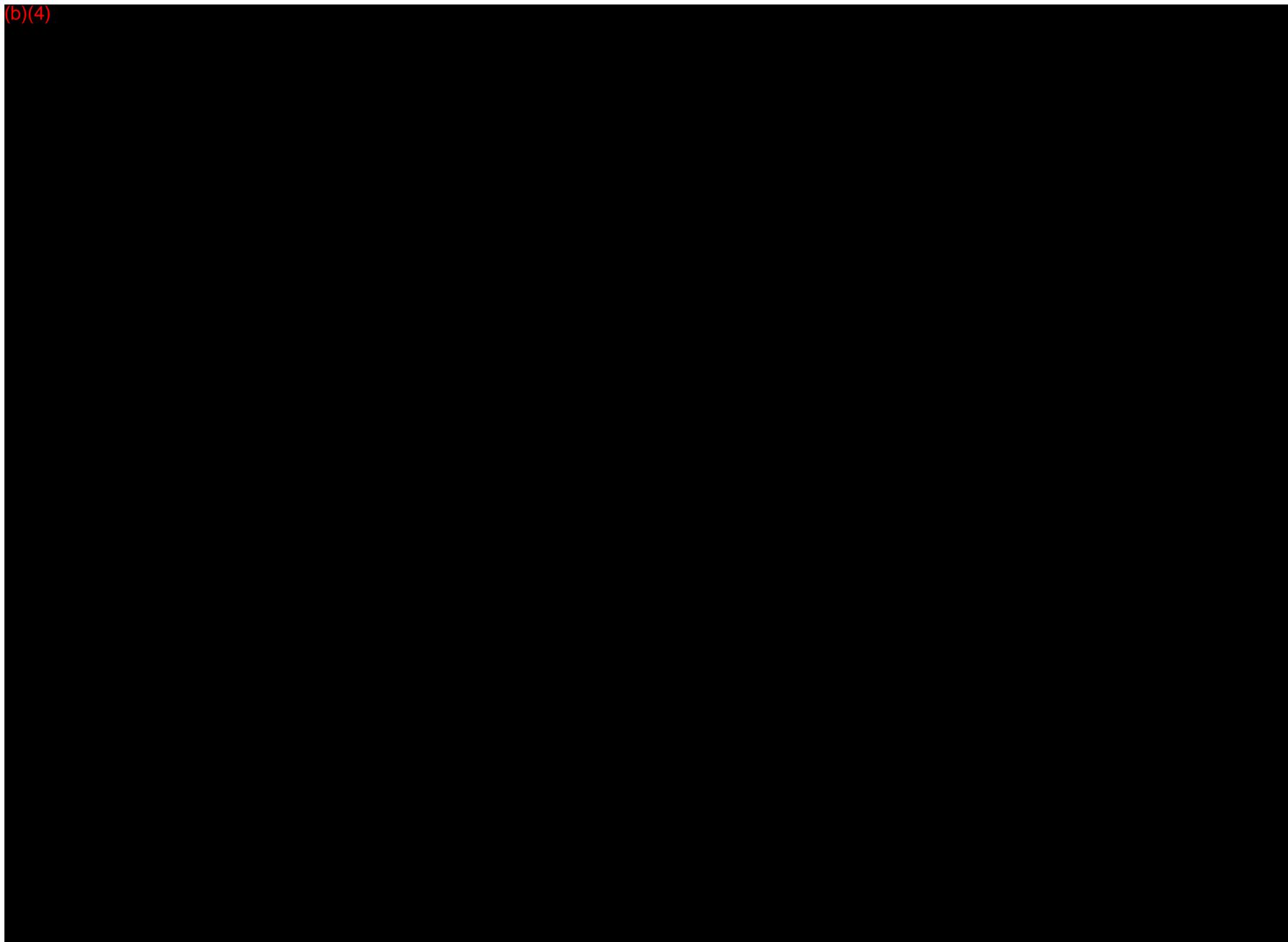
Drawing

(b)(4)



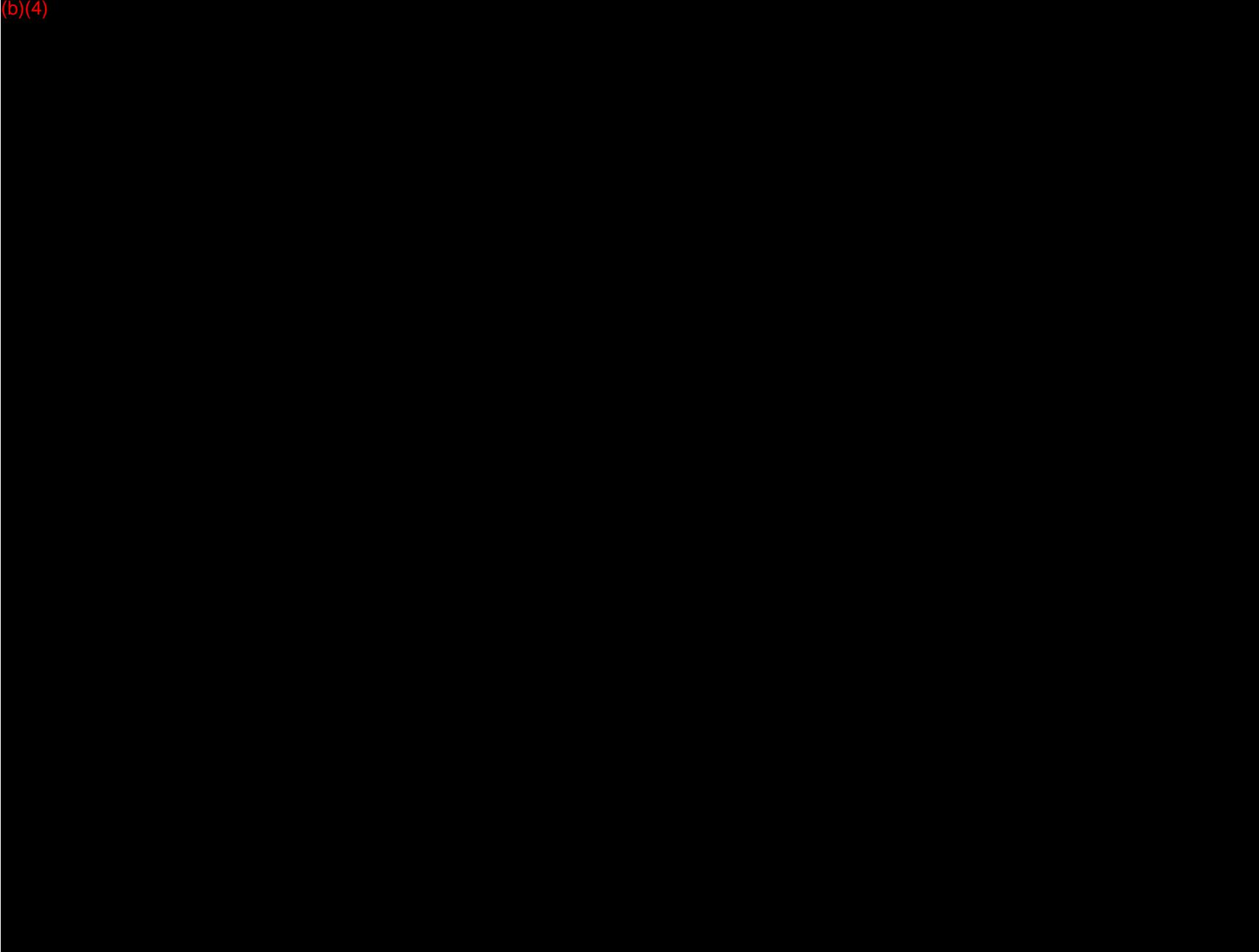
Drawing

(b)(4)



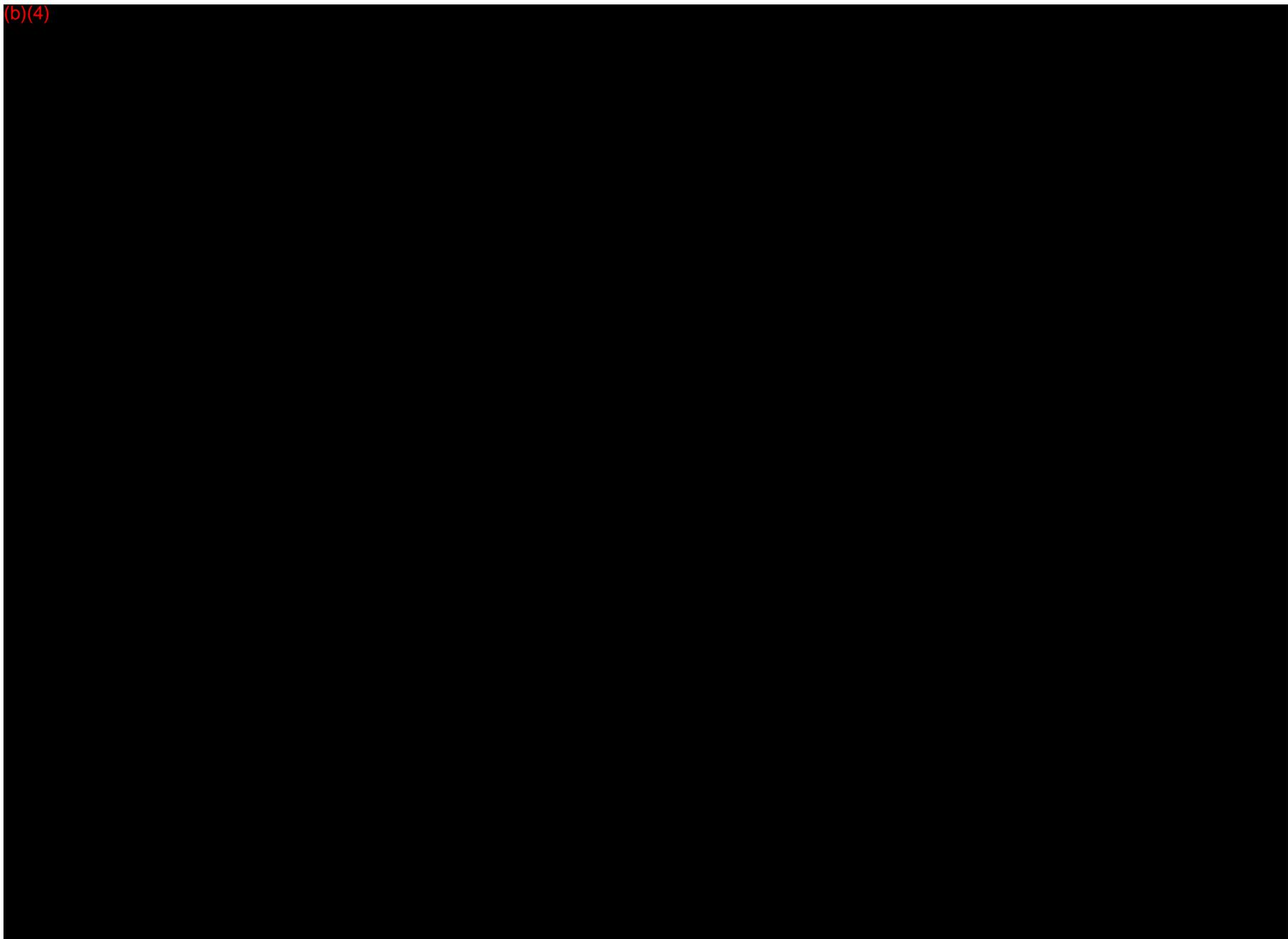
Drawing

(b)(4)



Drawing

(b)(4)



(b)(4)

Production

Revision

Appendix 18

 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>			
Document Number	Revision	Status	ECO No.
(b)(4)	(b)(4)	Production	(b)(4)
MediGuide Guidewire (b)(4) Drawing			
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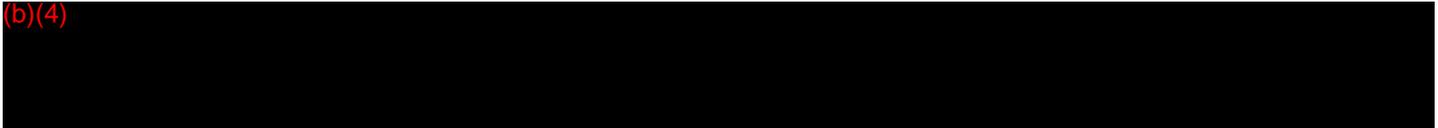
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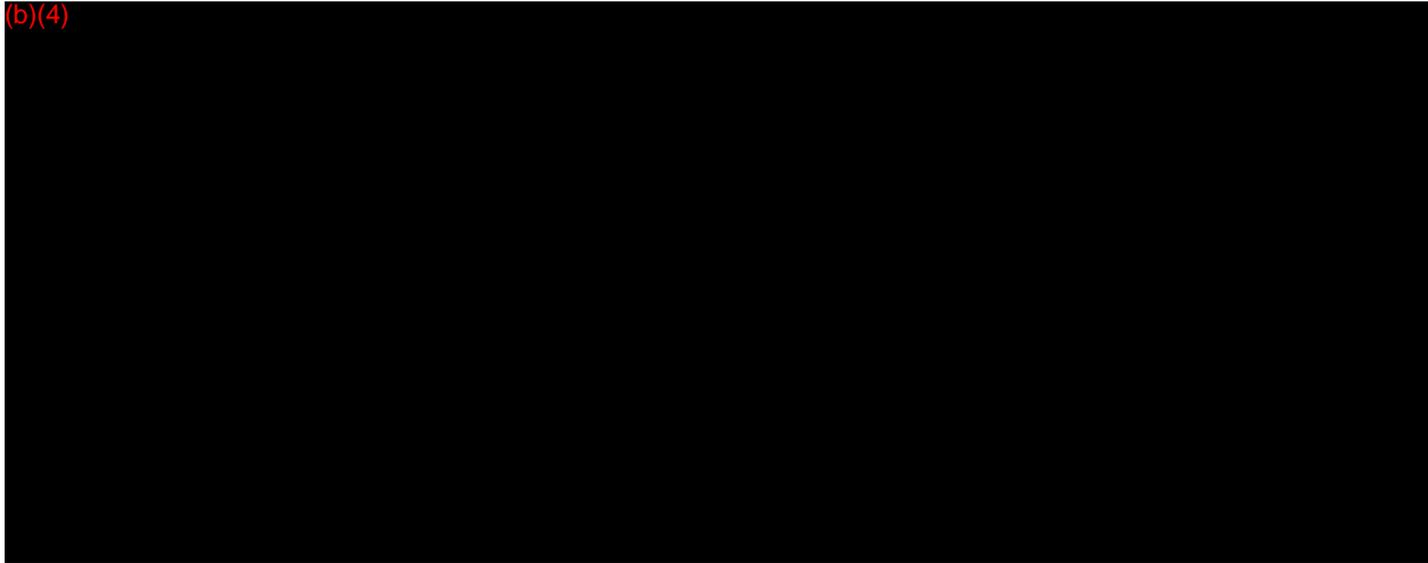
1.0 PURPOSE

(b)(4)

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2.0 SCOPE

(b)(4)

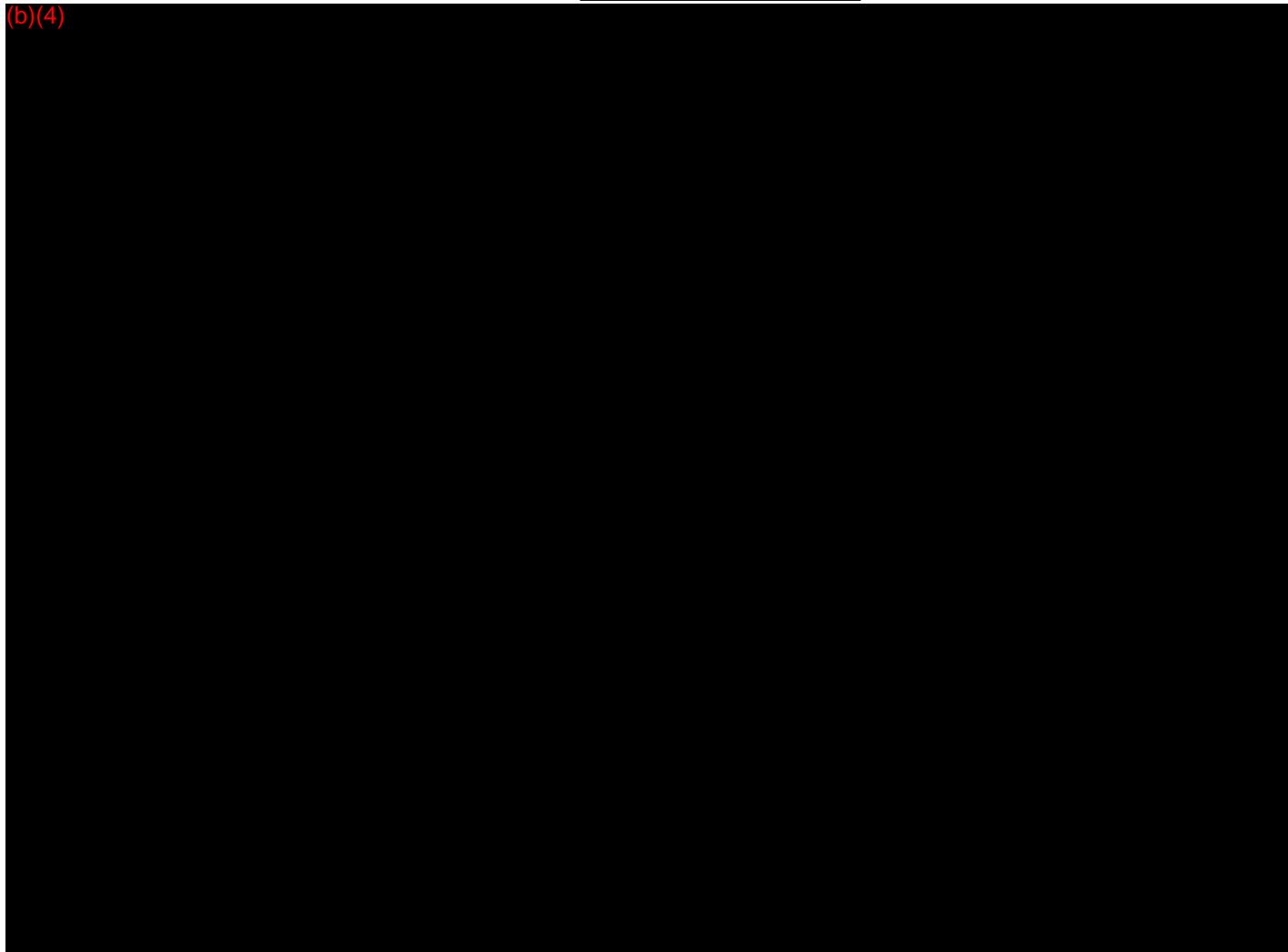
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3.0 LABELING

(b)(4)

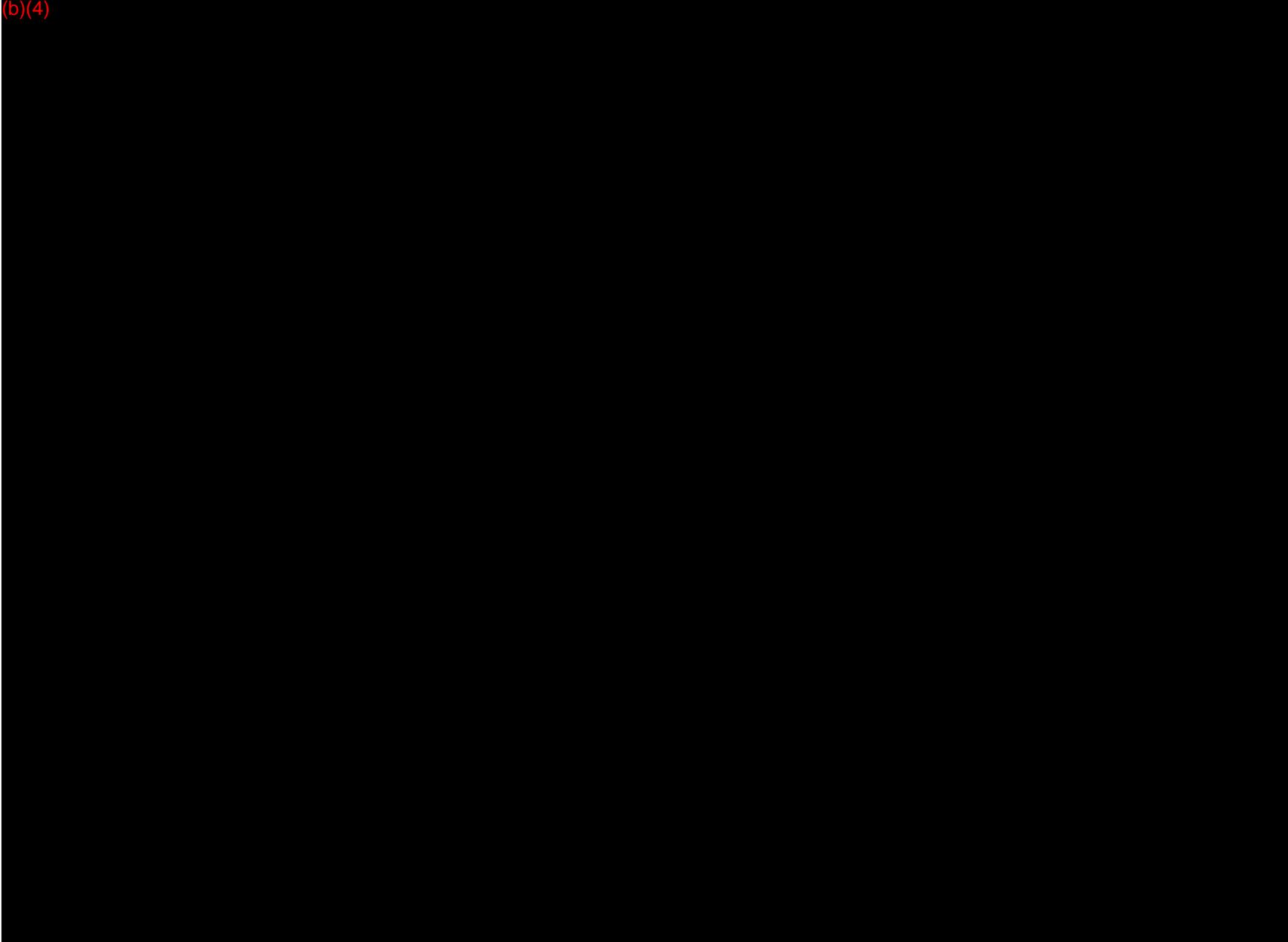
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Figure 1 – (b)(4)



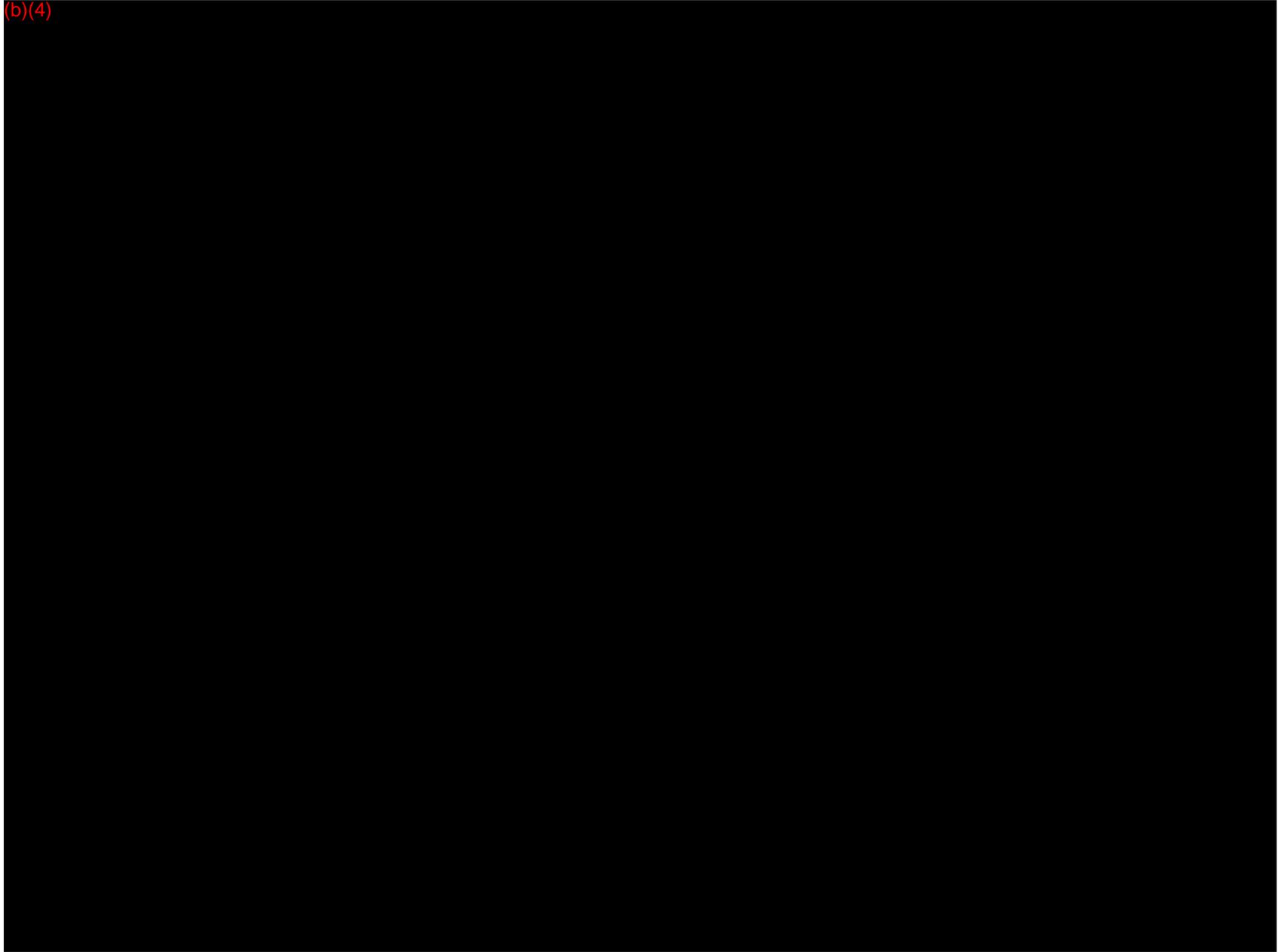
Drawing

(b)(4)



Drawing

(b)(4)

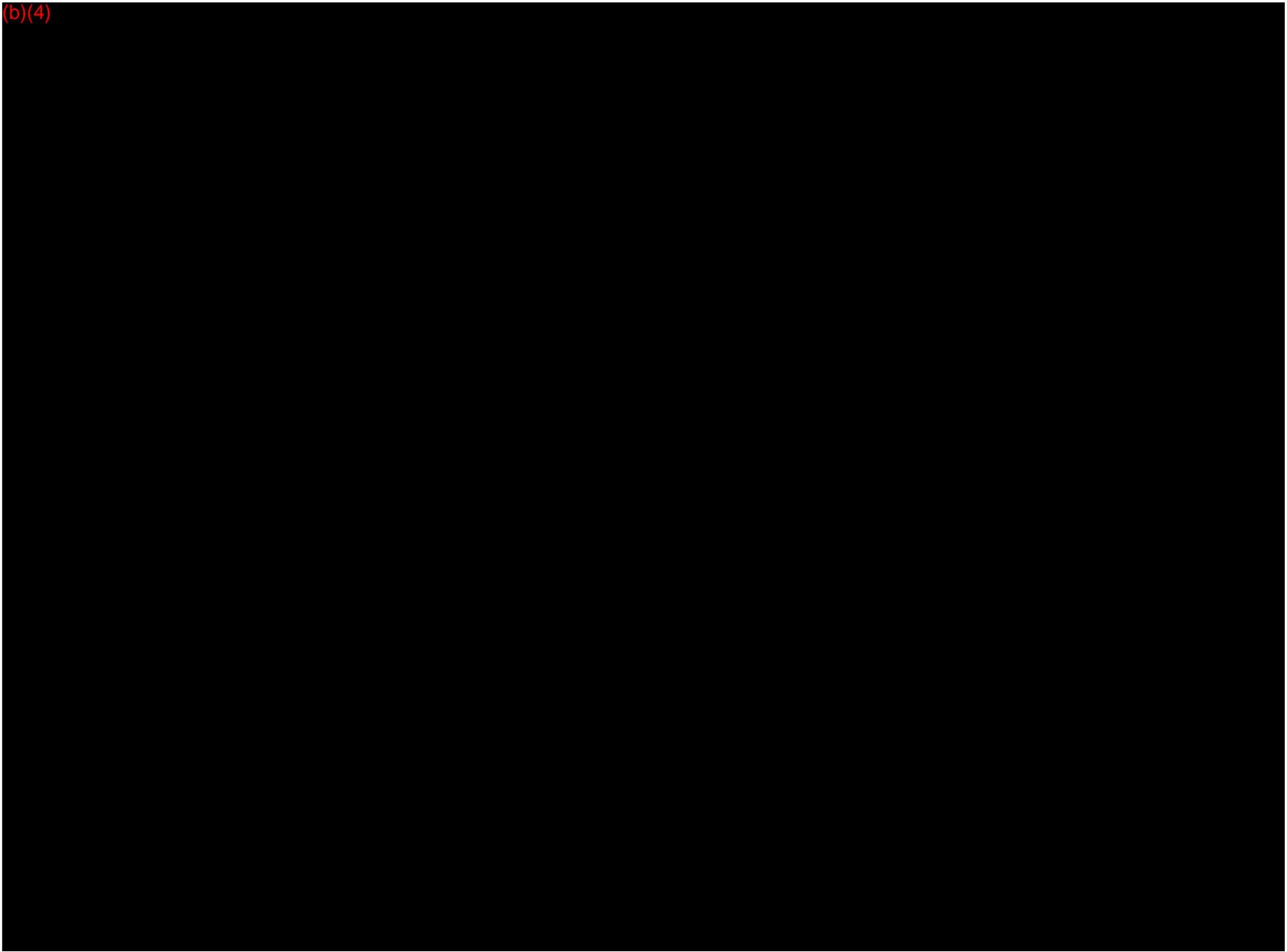


(b)(4)

Production

Revision

(b)(4)



(b)(4)

Appendix 19

(b)(4) Rev



Document Number	Revision	Status	ECO No.
(b)(4)	(b)(4)	Production	(b)(4)

MediGuide™ Guidewire (b)(4) **Drawing**

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1 Purpose

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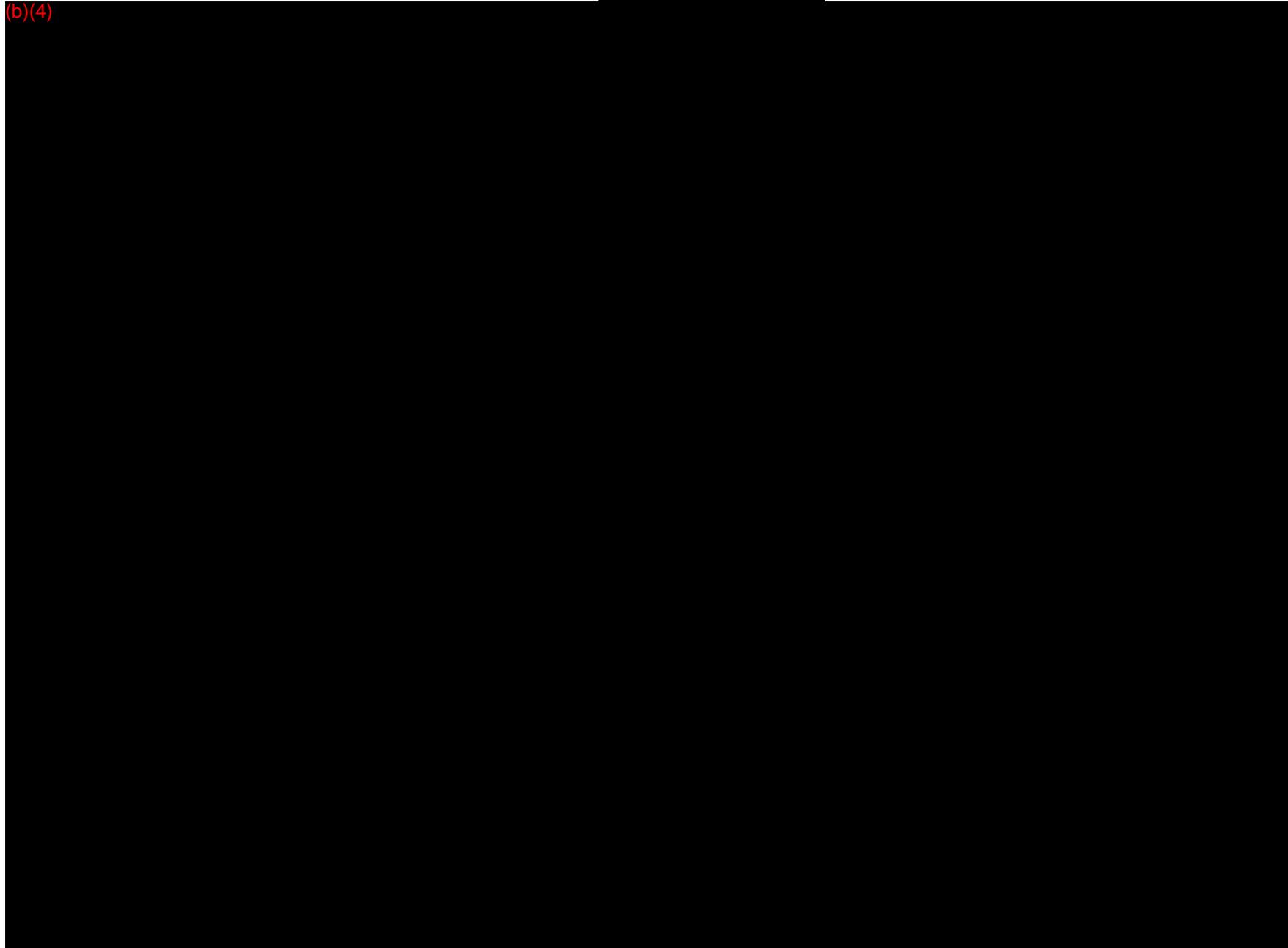
2 Scope

(b)(4)

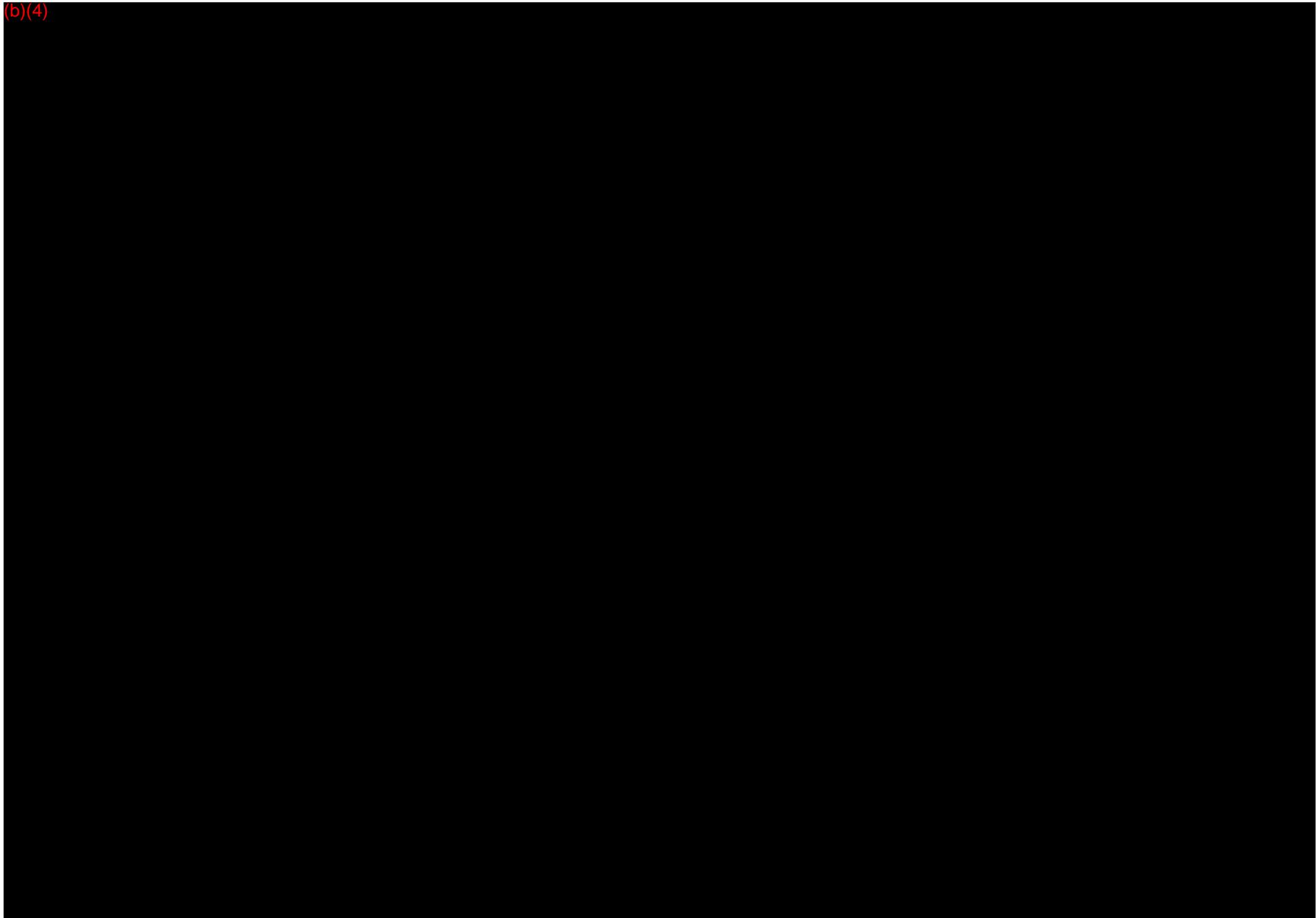
3 Labeling

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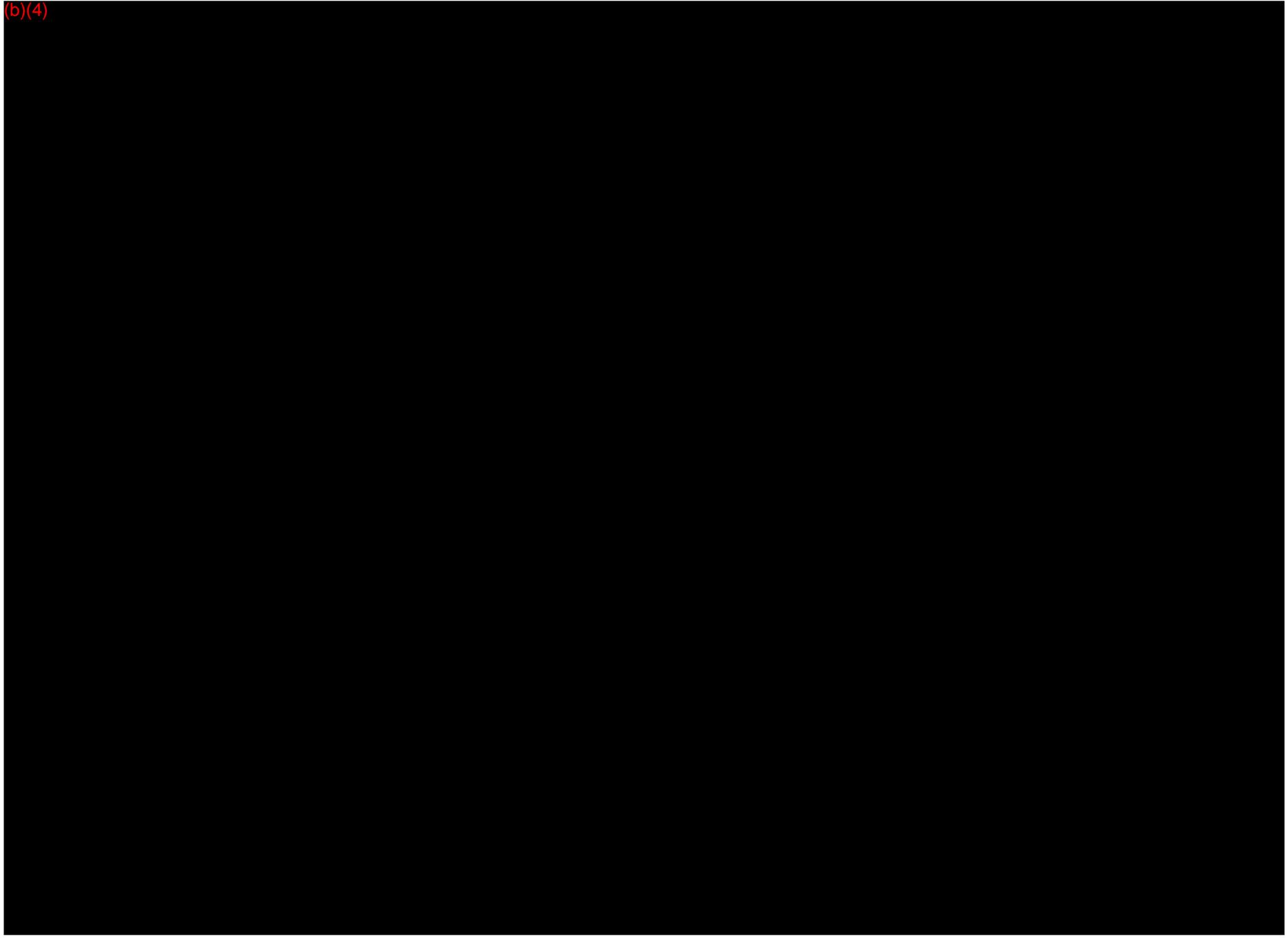


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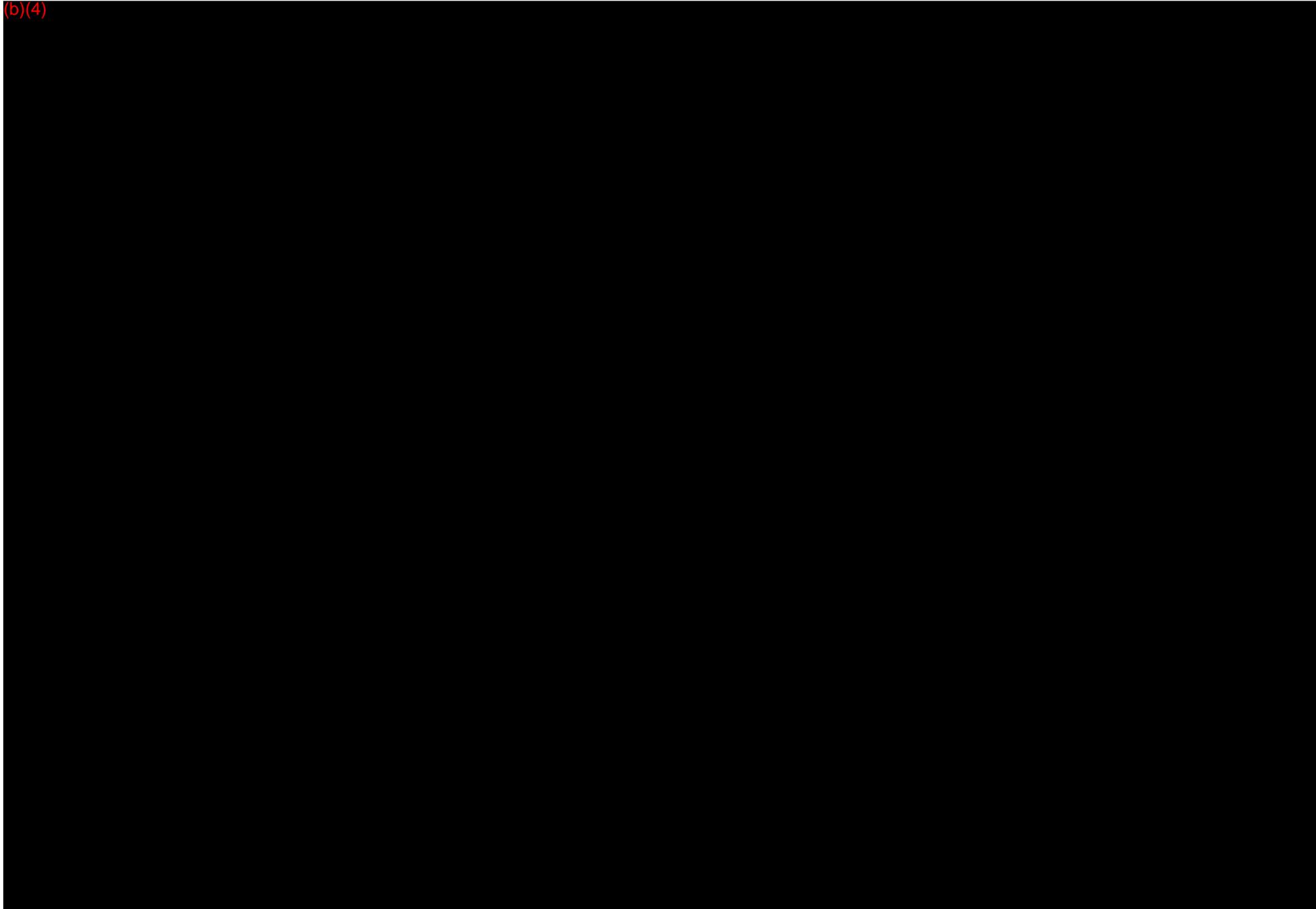
(b)(4)

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(b)(4)



(b)(4)

Appendix 20

CPS Excel™, MediGuide Enabled™
MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029
Instructions for Use



Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

ST. JUDE MEDICAL, the nine-squares symbol, and MORE CONTROL. LESS RISK, are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies.

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

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Description

The CPS Excel™, MediGuide Enabled™ guidewire is a MediGuide enabled guidewire with a hydrophilic coating. The CPS Excel, MediGuide Enabled guidewire contains a magnetic sensor allowing it be visualized using the MediGuide™ System. Refer to the product label for product specifications.

Model	Description
DS2M027	Soft
DS2M028	Medium
DS2M029	Extra-Firm

Package Contents

- One (1) guidewire
- One (1) torque tool
- One (1) J-straightener

Intended Use

The guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

Table 1. Accessories and their intended uses

Accessory	Intended Use
MediGuide Guidewire Torque Clip	Secure the left ventricular (LV) pacing lead and guidewire together. Torque the guidewire.
MediGuide Guidewire Connector	Connect the guidewire to the MediGuide Extension Cable.

Contraindications

The guidewire is not intended for use in the cerebral vasculature or patients judged not acceptable for percutaneous intervention (PCI).

Refer to the appropriate device manual for product specific contraindications that may apply.

Precautions

- Do not use if package is damaged.
- Do not re-sterilize.
- Do not reuse.
- Do not wipe with alcohol.

- Sterilized with ethylene oxide gas.
- Refer to instructions supplied with any interventional devices to be used in conjunction with this device for their intended uses, contraindications, and potential complications.
- Failure to follow the instructions may compromise guidewire performance and result in complications.
- Prior to use, read all labeling that accompanies the appropriate device being used and confirm guidewire compatibility.
- Thoroughly wet the guidewire before insertion or re-insertion to ensure proper activation of the hydrophilic coating.
- Always inspect the guidewire for damage prior to insertion or re-insertion.
- Do not advance devices with very short guidewire lumens over the distal floppy tip of the wire.
- Do not manipulate a guidewire that meets any resistance. Always determine the cause of any resistance and take any necessary remedial action before proceeding.
- Do not allow the guidewire tip to remain in a prolapsed position.
- Do not pre-shape the guidewire.
- Secure the MediGuide™ Guidewire Connector cable to the patient drapes.

Storage

Handle with care. Store in a well-ventilated area under conditions that protect the items from extreme temperatures and humidity. In addition, cartons containing these items should be protected from water and should not be crushed. Do not remove from outer box. Rotate stock regularly.

Instructions for Use

Note

In the event of sensor failure (loss of projection or projection fluctuation on the MediGuide™ System) use fluoroscopy to verify guidewire position.

1. Prepare the appropriate device according to the manufacturer's directions.
 2. Moisten the guidewire by flushing the guidewire dispenser prior to guidewire removal or manually wet after guidewire removal.
 3. Gently insert and advance the guidewire through the device to its distal tip using a J-straightener. If a MediGuide™ Guidewire Torque Clip is used, see Using a MediGuide™ Guidewire Torque Clip.
-

Note

A torque tool may be applied to the proximal end of the guidewire.

4. Advance the proximal end of the guidewire into the MediGuide™ Guidewire Connector until it stops. Tighten to securely attach the guidewire and connector.
5. Connect the proximal end of the MediGuide guidewire connector to the corresponding connector on the MediGuide™ Extension Cable. Refer to the MediGuide™ Technology User's Manual for instructions regarding MediGuide Enabled™ products.
6. Advance the guidewire into the desired location within the coronary or peripheral vasculature using fluoroscopy and the MediGuide™ System to facilitate proper guidewire placement.
7. Holding the guidewire in position, advance the device over the guidewire to the desired location.

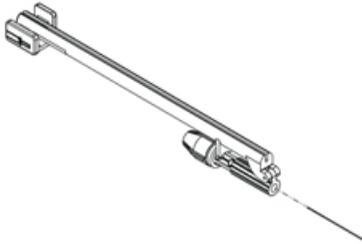
8. Complete the procedure, remove the guidewire and disconnect from the MediGuide system.

Using a Guidewire Torque Clip

A MediGuide™ Guidewire Torque Clip may be applied to the guidewire by locating the tip of the guidewire with the tip of the lead and using the clip to lock the guidewire and lead together. Locking of these tools enables real-time tip positioning and navigation of the non-MediGuide Enabled™ LV lead.

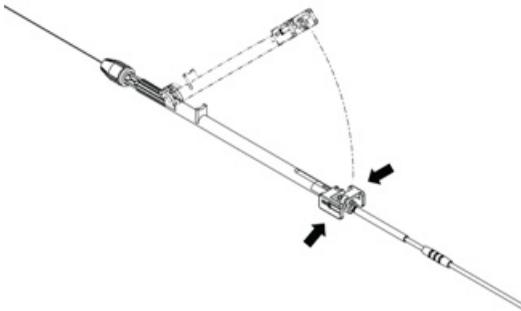
1. Loosen the nut on the clip.
2. Ensure the arm of the clip is raised and insert the guidewire into the clip.

Figure 1. Inserting the guidewire into the clip



3. Insert the guidewire through the lead to its distal tip.
4. Advance the guidewire until the distal end is approximately 1 cm beyond the lead tip.
5. Lower the arm of the clip. Press the finger tabs to place the end of the clip onto the lead connector.

Figure 2. Lowering the arm of the clip



6. Release the finger tabs to secure the clip to the lead connector.

7. Confirm a secure connection between the clip and the lead.
8. Withdraw the guidewire until the guidewire tip is just within the lead tip.
9. Tighten the nut on the clip.
10. To advance the guidewire past the lead tip, compress the finger tabs to remove the clip from the lead and advance the clip toward the lead connector pin.

Note

Do not torque the lead with the clip.
Remove the clip from the lead connector before torquing the guidewire.

11. Holding the guidewire in position, advance the lead over the guidewire.
12. To re-position the guidewire with the tip of the lead, compress the finger tabs and reconnect the clip to the lead connector.

Available Accessories

Additional accessories available for use with the guidewire include

- MediGuide™ Guidewire Torque Clip
 - MediGuide™ Guidewire Connector
 - MediGuide™ Extension Cable
-

WARNING

Vascular and/or cardiac perforation may occur during use. If resistance is encountered do not force the guidewire. Withdraw and inspect the guidewire carefully for signs of damage. Do not use the guidewire if it is kinked or damaged.

Reuse of a single-use device creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.

Cleaning, disinfection and re-sterilization may compromise essential material and design characteristics leading to device failure.

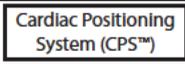
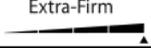
Symbols

The following symbols are used on the product or product packaging:

Table 2. Symbols

Symbol	Description
	Consult instructions for use
	Do not use if package is damaged
	Prescription only

Table 2. Symbols

Symbol	Description
	Cardiac Positioning System (CPS™)
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using ethylene oxide
	Do not reuse
	Date of Manufacture
	Manufacturer
LOT	Lot number
	Temperature limitations
Soft 	Soft
Medium 	Medium
Extra-Firm 	Extra firm
	Inside/outside diameter of guidewire
EC REP	Authorized EC Representative in the European Community
CE 0123	Affixed in accordance with European Council Directive 90/385/EEC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.

U.S. Limited Warranty and Disclaimer

St. Jude Medical (SJM) hereby warrants that if this SJM product fails to perform with normal tolerances for a patient due to a defect in materials 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:

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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 BEFORE' date marked on the packaging of the product.

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100066519



January 2012
Art 60037211/A



0125
2012

Appendix 21

Model DS2M031

Instructions for Use



Proposition 65, a State of California voter initiative, requires the following notice:

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

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Description

The St. Jude Medical™ MediGuide™ Extension Cable is a flexible, insulated cable that is used to connect MediGuide Enabled™ products to the MediGuide™ System. The cable is compatible for single use only.

The following are devices that connect to the cable:

Table 1. Connecting Equipment

Device	Model
CPS Aim, MediGuide Enabled Inner Catheter	DS2M024, DS2M025, DS2M026
CPS Direct, MediGuide Enabled Outer Catheter	DS2M021, DS2M022, DS2M023
MediGuide Guidewire Connector	DS2M032
MediGuide Cath Connect	IB 892928-00

Package Contents

- One (1) extension cable

Intended Use

The MediGuide™ Extension Cable is intended for use with St. Jude Medical™ MediGuide Enabled™ products.

Precautions

- Personnel handling the MediGuide™ Extension Cable should wear gloves.

Packaging and Shelf Life

The packaging is designed to provide aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. Contents are sterile if package is unopened and undamaged. The expiration date is marked on the outside of the package.

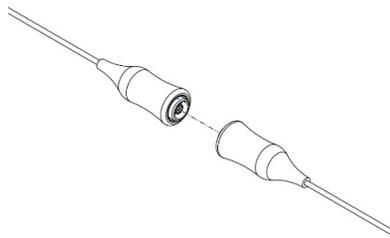
Storage

Handle with care. Store in a well-ventilated area under conditions that protect these items from extreme temperatures and humidity. In addition, cartons containing these items should be protected from water and should not be crushed. Do not remove from outer box. Rotate stock regularly.

Instructions for use

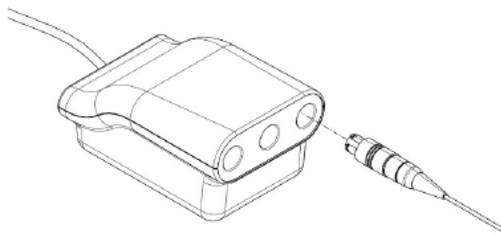
- Inspect the cables carefully for integrity and overall condition.
- Plug the MediGuide™ Extension Cable device connector ends to the MediGuide Enabled™ devices.

Figure 1. Plugging the connector ends



- Plug the MediGuide extension cable system connector ends to the MediGuide™ Cath Connect.

Figure 2. Connecting to the MediGuide Cath Connect



4. When connecting to the MediGuide system, refer to the MediGuide™ Technology User's Manual for instructions regarding MediGuide Enabled™ products.

Note

The device connector ends and the system connector ends are color coded.

Symbols

The following symbols are used on the product or product packaging:

Table 2. Symbols

Symbol	Definition
	Consult instructions for use
	Do not use if package is damaged
R ONLY	Prescription only
	Keep away from sunlight
	Keep dry
	Do not reuse
STERILE EO	Sterilized using ethylene oxide
	Use by
	Date of Manufacture
	Manufacturer
LOT	Lot number
	Temperature limits
EC REP	Authorized EC Representative in the European Community
CE 0123	Affixed in accordance with European Council Directive 90/385/EEC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.

St. Jude Medical (SJM) hereby warrants that if this SJM product fails to perform with normal tolerances for a patient due to a defect in materials 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 designed and distributed 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 BEFORE' date marked on the packaging of the product.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA or 301-796-8118

January 2012
Art 60040831/A

6125
2012

Appendix 22

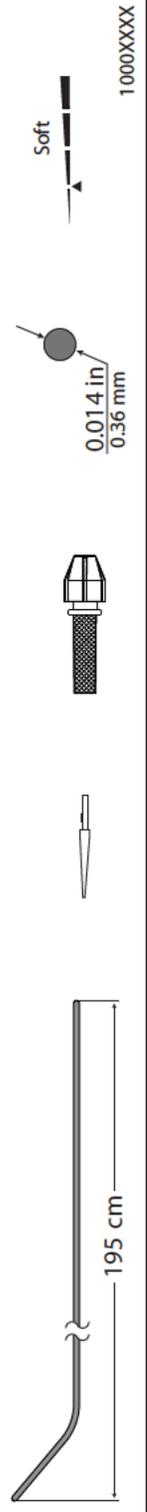
Box Label

Cardiac Positioning System (EPS™)

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Soft

- (AR) سلك التوجيه، لين
- (CS) Vodící drát MediGuide Enabled™, měkký
- (DA) MediGuide Enabled™ guidewire, blød
- (DE) MediGuide Enabled™ Führungsdraht, weich
- (EL) Οδηγός σύρμα MediGuide Enabled™, μαλακό
- (ES) Guía MediGuide Enabled™, flexible
- (ET) MediGuide Enabled™ juhtetraat, pehme
- (FI) MediGuide Enabled™ -ohjainlanka, taipuisa
- (FR) Fil-guide MediGuide Enabled™, Souple
- (HU) MediGuide Enabled™ veze tődrót, puha
- (IT) Guida MediGuide Enabled™, Morbida
- (JA) MediGuide Enabled™ ガイドワイヤ、ソフト
- (KO) MediGuide Enabled™ 가이드 와이어, 소프트
- (LT) „MediGuide Enabled™“ kreipiamoji viela, minkšta
- (NL) MediGuide Enabled™ voerdraad, flexibel
- (NO) MediGuide Enabled™ Guidewire, myk
- (PL) Elastyczny prowadnik MediGuide Enabled™
- (PT) Guia MediGuide Enabled™, Suave
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- (SK) Vodič MediGuide Enabled™, mäkký
- (SR) MediGuide Enabled™ vodič žica, mekana
- (SV) MediGuide Enabled™ Styrtråd, mjuk
- (TR) MediGuide Enabled™ Kilavuz Tel, Yumuşak
- (ZH) MediGuide Enabled™ 引导导丝, 软

DS2M027 195 cm Use Before: 20XX-XX-XX  LOT Manufacturing Date: 20XX-XX-XX  LOT Number: SAMPLE1



STERILE EO Contents of this package have been ethylene oxide sterilized.  Do not use if package is damaged.  Do not reuse.  Consult instructions for use.  Keep away from sunlight.  Keep dry.  CE Only 0123 Made in Sweden.

Use Before: 20XX-XX-XX  LOT SAMPLE1

GTIN: 06414734000007  (01)05414734000000 (17)000000(10)1234567

Lot Number: 20XX-XX-XX  LOT SAMPLE1

 **SAMPLE** +\$31.004.311.234.567.8.9.1P

 **SAMPLE** +H758DS2M0.070L

 **EC REP** St. Jude Medical AB
Veddstavägen 19
SE-175 84 Järfälla
Sweden
Tel. +46 8 474 4000
Fax. +46 8 760 95 42

 **Manufacturer** St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sydney, CA 91342 USA
+1 818 362 6822
800.722.3774 (US only)

 **ST. JUDE MEDICAL**
MORE CONTROL. LESS RISK.

Pouch Label

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Soft

<p>(AR) سلك التوجيه، لين</p> <p>(CS) Vodící drát MediGuide Enabled™, měkký</p> <p>(DA) MediGuide Enabled™ guidewire, blød</p> <p>(DE) MediGuide Enabled™ Führungsdraht, weich</p> <p>(EL) Οδηγός σύρμα MediGuide Enabled™, μαλακό</p> <p>(ES) Guía MediGuide Enabled™, flexible</p> <p>(ET) MediGuide Enabled™ juhtetraat, pehme</p> <p>(FI) MediGuide Enabled™ -ohjainlanka, taipuissa</p>	<p>(FR) Fil-guide MediGuide Enabled™, Souple</p> <p>(HU) MediGuide Enabled™ vezetődrót, puha</p> <p>(IT) Guida MediGuide Enabled™, Morbida</p> <p>(JA) MediGuide Enabled™ ガイドワイヤ、ソフト</p> <p>(KO) MediGuide Enabled™ 가이드와이어, 소프트</p> <p>(LT) „MediGuide Enabled™“ kreipiamoji viela, minkšta</p> <p>(NL) MediGuide Enabled™ voerdraad, flexibel</p> <p>(NO) MediGuide Enabled™ Guidewire, myk</p>	<p>(PL) Elastyczny przewodnik MediGuide Enabled™</p> <p>(PT) Guia MediGuide Enabled™, Suave</p> <p>(RU) Проводник MediGuide Enabled™, мягкий</p> <p>(SK) Vodič MediGuide Enabled™, mäkký</p> <p>(SR) MediGuide Enabled™ vodič žica, mekana</p> <p>(SV) MediGuide Enabled™ Styrtråd, mjuk</p> <p>(TR) MediGuide Enabled™ Kilavuz Tel, Yumuşak</p> <p>(ZH) MediGuide Enabled™ 导引导丝，软</p>
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Cardiac Positioning System (CPS™)

Use Before: 20XX-XX-XX

LOT: 20XX-XX-XX

Manufacturing Date: 20XX-XX-XX

LOT Number: SAMPLE1

195 cm

195 cm

0.014 in / 0.36 mm

Soft

1000XXXX

STERILE EO Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.

Do not reuse.

Consult instructions for use.

Keep away from sunlight.

Keep dry.

Made in Sweden.

CE Only 0123

DS2M027 / 195

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Soft

GTIN: 05414734000000
+443100431123456789LP

Use Before: 20XX-XX-XX

LOT: SAMPLE1

St. Jude Medical

DS2M027 / 195

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Soft

GTIN: 05414734000000
(01)05414734000000(17)000000(10)1234567

Use Before: 20XX-XX-XX

LOT: SAMPLE1

St. Jude Medical

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sydney, CA 91342 USA
+1 818 362 6822
900.722.3774 (US only)

St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
Sweden
Tel. +46 8 474 4000
Fax. +46 8 760 95 42

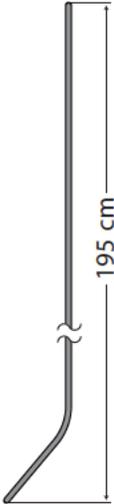
Box Label

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Medium

(AR) متوسط، MediGuide Enabled™ 가이드 와이어, 미디엄
 (CS) Vodící drát MediGuide Enabled™, středně tuhý
 (DA) MediGuide Enabled™ guidewire, medium
 (DE) MediGuide Enabled™ Führungsdraht, mittel
 (EL) Οδηγός σύρμα MediGuide Enabled™, μεσαίο
 (ES) Guía MediGuide Enabled™, media
 (ET) MediGuide Enabled™ juhtetraat, keskmine
 (FI) MediGuide Enabled™ -ohjainlanka, keskijäykkä
 (FR) Fil-guide MediGuide Enabled™, Moyen
 (HU) MediGuide Enabled™ vezeződrót, közepes
 (IT) Guida MediGuide Enabled™, Media
 (JA) MediGuide Enabled™ ガイドワイヤ、ミディアム

(KO) MediGuide Enabled™ 가이드 와이어, 미디엄
 (LT) „MediGuide Enabled™“ kreipiamoji viela, vidutinio standumo
 (NL) MediGuide Enabled™ voerdraad, medium
 (NO) MediGuide Enabled™ Guidewire, medium
 (PL) Prowadnik MediGuide Enabled™ o średniej sztywności
 (PT) Guia MediGuide Enabled™, Médio
 (RU) Проводник MediGuide Enabled™, средней жесткости
 (SK) Vodič MediGuide Enabled™, stredný
 (SR) MediGuide Enabled™ vodič žica, srednja
 (SV) MediGuide Enabled™ Styrtråd, medium
 (TR) MediGuide Enabled™ Kilavuz Tel, Orta
 (ZH) MediGuide Enabled™ 导引导丝, 中

DS2M028 195 cm



Use Before: 20XX-XX-XX **LOT** LOT Number: SAMPLE1



0.014 in
0.36 mm



Medium

1000XXXX

STERILE EO Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.

Do not reuse.

Consult instructions for use.

Keep away from sunlight.

Keep dry.

GTIN: 06414734000007
 (01)05414734000000 (17)000000(10)1234567

Use Before: 20XX-XX-XX **LOT** LOT Number: SAMPLE1

Made in Sweden.

CE Only 0123

St. Jude Medical
 Cardiac Rhythm Management Division
 15900 Valley View Court
 Sylmar, CA 91342 USA
 +1 818 362 6822
 800.722.3774 (US only)

St. Jude Medical AB
 Veddestavägen 19
 SE-175 84 Järfälla
 Sweden
 Tel. +46 8 474 4000
 Fax. +46 8 760 95 42

Pouch Label

Cardiac Positioning System (EPS™)

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Medium

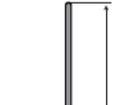
(AR) سلك التوجيه، متوسط (CS) Vodicí drát MediGuide Enabled™, středně tuhý (DA) MediGuide Enabled™ guidewire, medium (DE) MediGuide Enabled™ Führungsdraht, mittel (EL) Οδηγό σύριος MediGuide Enabled™, μεσαίο (ES) Guía MediGuide Enabled™, media (ET) MediGuide Enabled™ juhtetraat, keskmine (FI) MediGuide Enabled™ -ohjaimlanka, keskijäykkä	(FR) Fil-guide MediGuide Enabled™, Moyen (HU) MediGuide Enabled™ vezetőrót, közepes (IT) Guida MediGuide Enabled™, Media (JA) MediGuide Enabled™ ガイドワイヤ、ミディアム (KO) MediGuide Enabled™ 가이드 와이어, 미디엄 (LT) „MediGuide Enabled™“ kreipiamoji viela, vidutinio standumo (NL) MediGuide Enabled™ voerdraad, medium (NO) MediGuide Enabled™ Guidewire, medium	(PL) Prowadnik MediGuide Enabled™ o średniej sztywności (PT) Guia MediGuide Enabled™, Médio (RU) Проводник MediGuide Enabled™, средней жесткости (SK) Vodič MediGuide Enabled™, stredný (SR) MediGuide Enabled™ vodič žica, srednja (SV) MediGuide Enabled™ Styrtråd, medium (TR) MediGuide Enabled™ Kilavuz Tel, Orta (ZH) MediGuide Enabled™ 引导导丝, 中
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Use Before: 20XX-XX-XX **LOT** 20XX-XX-XX **LOT** SAMPLE1

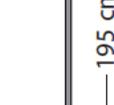
Manufacturing Date: 20XX-XX-XX **LOT** 20XX-XX-XX **LOT** SAMPLE1



0.014 in
0.36 mm



Medium



1000XXXX

STERILE EO Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.

Do not reuse.

Consult instructions for use.

Keep away from sunlight.

Keep dry.

Made in Sweden.

DS2M028 / 195 cm

195 cm

CE Only 0123

DS2M028 / 195
CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Medium

Use Before: 20XX-XX-XX **LOT** SAMPLE1

GTIN: 05414734000000 (17)000000 (10)1234567

Lot Number: DS2M028/195

DS2M028 / 195
CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Medium

Use Before: 20XX-XX-XX **LOT** SAMPLE1

GTIN: 05414734000000 (17)000000 (10)1234567

Lot Number: DS2M028/195

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sydney, CA 91342 USA
+1 818 362 6822

St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
Sweden
Tel. +46 8 474 4000
Fax. +46 8 760 95 42

Box Label

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Extra-Firm

(AR) مسلك التوجيه، MediGuide Enabled™ فاتق الصلابة
 (CS) Vodící drát MediGuide Enabled™, extra tuhý
 (DA) MediGuide Enabled™ guidewire, ekstrastiv
 (DE) MediGuide Enabled™ Führungsdraht, extra-fest
 (EL) Οδηγός σύρμα MediGuide Enabled™, εξαιρετικά σταθερό
 (ES) Guía MediGuide Enabled™, extra-rígida
 (ET) MediGuide Enabled™ juhtetraat, eriti jäik
 (FI) MediGuide Enabled™ -ohjainlanka, erittäin jäykkä
 (FR) Fil-guide MediGuide Enabled™, Extra-rigide
 (HU) MediGuide Enabled™ vezetörót, extrakemény
 (IT) Guida MediGuide Enabled™, Extra-rigida
 (JA) MediGuide Enabled™ ガイドワイヤ、エクストラ フォーム

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 (NO) MediGuide Enabled™ Guidewire, ekstra stiv
 (PL) Bardzo sztywny przewodnik MediGuide Enabled™
 (PT) Guia MediGuide Enabled™, Extra-firme
 (RU) Проводник MediGuide Enabled™, особо жесткий
 (SK) Vodič MediGuide Enabled™, extra pevný
 (SR) MediGuide Enabled™ vodič žica, veoma čvrsta
 (SV) MediGuide Enabled™ Stytråd, extra styv
 (TR) MediGuide Enabled™ Kilavuz Tel, Ekstra Sert
 (ZH) MediGuide Enabled™ 导引导丝，特硬

DS2M029 195 cm Use Before: 20XX-XX-XX LOT LOT Number: SAMPLE1

1000XXXX Extra-Firm

195 cm 0.014 in / 0.36 mm

50°C / 122°F Keep away from sunlight. keep dry. Only Made in Sweden.

Do not use if package is damaged. Do not reuse. Consult instructions for use.

Contents of this package have been ethylene oxide sterilized.

STERILE EO SAMPLE +H758DS2M070L

Use Before: 20XX-XX-XX SAMPLE Lot Number: 20XX-XX-XX LOT SAMPLE1

+8758DS2M070L SAMPLE +8758DS2M070L

GTIN: 0641473400000X SAMPLE (01)05414734000000(17)000000(10)1234567

St. Jude Medical
 Cardiac Rhythm Management Division
 15900 Valley View Court
 Sylmar, CA 91342 USA
 +1 818 362 6822
 800.722.3774 (US only)

St. Jude Medical AB
 Veddestavägen 19
 SE-17584 Järfälla
 Sweden
 Tel. +46 8 474 4000
 Fax. +46 8 760 95 42

EC REP

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Pouch Label

CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Extra-Firm

Cardiac Positioning System (EPS™)

(AR) فائق الصلابة. MediGuide Enabled™, extra tuhyí

(CS) Vodicí drát MediGuide Enabled™, extra tuhyí

(DA) MediGuide Enabled™ guidewire, ekstrastiv

(DE) MediGuide Enabled™ Führungsdraht, extra-fest

(EL) Οδηγός σύρμα MediGuide Enabled™, εξαιρετικά σθερό

(ES) Guía MediGuide Enabled™, extra-rígida

(ET) MediGuide Enabled™ juhtetraat, eriti jäik

(FI) MediGuide Enabled™ -ohjainlanka, erittäin jäykkä

(FR) Fil-guide MediGuide Enabled™, Extra-rigide

(HU) MediGuide Enabled™ vezetődrót, extrakemény

(IT) Guida MediGuide Enabled™, Extra-rigida

(JA) MediGuide Enabled™ ガイドワイヤ, エクストラ フォーム

(KO) MediGuide Enabled™ 가이드 와이어, 엑스트라 펌

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(NO) MediGuide Enabled™ Guidewire, ekstra stiv

(PL) Bardzo sztywny przewodnik MediGuide Enabled™

(PT) Guia MediGuide Enabled™, Extra-firme

(RU) Проводник MediGuide Enabled™, особо жесткий

(SK) Vodič MediGuide Enabled™, extra pevný

(SR) MediGuide Enabled™ vodič žica, veoma čvrsta

(SV) MediGuide Enabled™ Sstyrtråd, extra styv

(TR) MediGuide Enabled™ Kilavuz Tel, Ekstra Sert

(ZH) MediGuide Enabled™ 导引导丝, 特硬

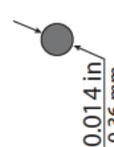
Use Before: 20XX-XX-XX

195 cm

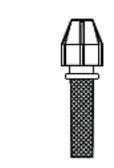
Manufacturing Date: 20XX-XX-XX

LOT

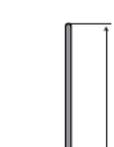
LOT Number: SAMPLE1



0.014 in
0.36 mm



Extra-Firm



195 cm

STERILE EO Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.

Do not reuse.

Consult instructions for use.

Keep away from sunlight.

Keep dry.

50°C 122°F

-5°C 23°F

CE

Made in Sweden.

Only 0123

DS2M029/195
CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Extra-Firm

GTIN: 05414734000000
+443100431123456789LP

DS2M029/195
CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Extra-Firm

GTIN: 05414734000000
+1758DS2M070L

DS2M029/195
CPS EXCEL™, MEDIGUIDE ENABLED™
MediGuide Enabled™ Guidewire, Extra-Firm

GTIN: 05414734000000
+1758DS2M070L

Lot Number: SAMPLE1

Lot Number: SAMPLE1

Lot Number: SAMPLE1

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sydney, CA 91342 USA
+1 818 362 6822
900.722.3774 (US, only)

St. Jude Medical AB
Veddstravägen 19
SE-17584 Järfälla
Sweden
Tel. +46 8 474 4000
Fax. +46 8 760 95 42

St. Jude Medical
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Appendix 23

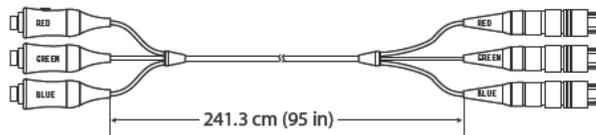
Box Label

MEDIGUIDE™ EXTENSION CABLE

- | | |
|------------------------------------|---------------------------------------|
| (AR) MediGuide™ كبل الإطالة | (KO) MediGuide™ 연장 케이블 |
| (CS) Prodlužovací kabel MediGuide™ | (LT) „MediGuide™“ ilginamasis kabelis |
| (DA) MediGuide™ forlænger kabel | (NL) MediGuide™ verlengsnoer |
| (DE) MediGuide™ Verlängerungskabel | (NO) MediGuide™ Forlengelseskabel |
| (EL) Καλώδιο επέκτασης MediGuide™ | (PL) Przewód przedłużający MediGuide™ |
| (ES) Cable prolongador MediGuide™ | (PT) Cabo de extensão MediGuide™ |
| (ET) MediGuide™ pikenduskaabel | (RU) Удлинительный кабель MediGuide™ |
| (FI) MediGuide™-jatkojohto | (SK) Predlžovací kábel MediGuide™ |
| (FR) Câble de rallonge MediGuide™ | (SR) MediGuide™ produžni kabl |
| (HU) MediGuide™ hosszabítókábel | (SV) MediGuide™ Förlängningskabel |
| (IT) Prolunga MediGuide™ | (TR) MediGuide™ Uzatma Kablo |
| (JA) MediGuide™ 延長ケーブル | (ZH) MediGuide™ 延长电缆 |

DS2M031

LOT LOT Number:



100067050

Use Before:

Manufacturing Date:

STERILE EO
Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged. Do not reuse. Consult instructions for use.

50°C 122°F
-5°C 23°F

Keep away from sunlight. Keep dry. **Rx Only** Made in USA

Manufacturer
St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822
800 722 3774 (US only)

EC REP
St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
Sweden
Tel. +46 8 474 40 00
Fax. +46 8 760 95 42

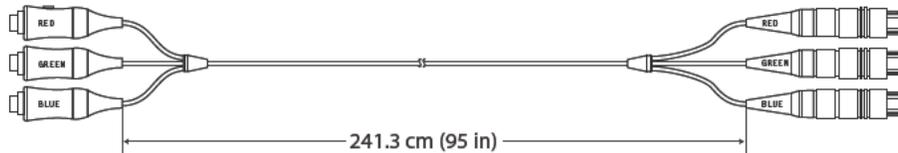
ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

MEDIGUIDE™ EXTENSION CABLE

- | | |
|------------------------------------|---------------------------------------|
| (AR) MediGuide™ كبل الإطالة | (KO) MediGuide™ 연장 케이블 |
| (CS) Prodlužovací kabel MediGuide™ | (LT) „MediGuide™“ ilginamasis kabelis |
| (DA) MediGuide™ forlænger kabel | (NL) MediGuide™ verlengsnoer |
| (DE) MediGuide™ Verlängerungskabel | (NO) MediGuide™ Forlængelses kabel |
| (EL) Καλώδιο επέκτασης MediGuide™ | (PL) Przewód przedłużający MediGuide™ |
| (ES) Cable prolongador MediGuide™ | (PT) Cabo de extensão MediGuide™ |
| (ET) MediGuide™ pikenduskaabel | (RU) Удлинительный кабель MediGuide™ |
| (FI) MediGuide™-jatkokohto | (SK) Predlžovací kábel MediGuide™ |
| (FR) Câble de rallonge MediGuide™ | (SR) MediGuide™ produžni kabl |
| (HU) MediGuide™ hosszabbítókábel | (SV) MediGuide™ Förlängningskabel |
| (IT) Prolunga MediGuide™ | (TR) MediGuide™ Uzatma Kablosu |
| (JA) MediGuide™ 延長ケーブル | (ZH) MediGuide™ 延长电缆 |

DS2M031

LOT LOT Number:



100067050

Use Before:

Manufacturing Date:

STERILE EO

Contents of this package have been ethylene oxide sterilized.



Do not use if package is damaged.



Do not reuse.



Consult instructions for use.

50°C
122°F
-5°C
23°F



Keep away from sunlight.



Keep dry.

R
Only

Made in USA

Manufacturer
St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822
800 722 3774 (US only)

EC REP

St. Jude Medical AB
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SE-175 84 Järfälla
Sweden
Tel. +46 8 474 40 00
Fax. +46 8 760 95 42

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Pouch Label

Box Label

(91)ZFIN#(92)MODEL#(17)YYMMDD(10)SAMPL#E001(30)DT



For Internal Purposes Only

DS2M031

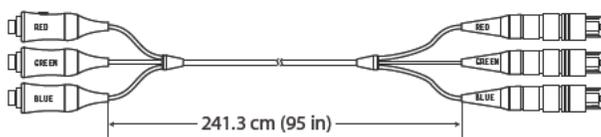
MEDIGUIDE™ EXTENSION CABLE

MEDIGUIDE™ EXTENSION CABLE

(AR) MediGuide™ كبل الإطالة	(KO) MediGuide™ 연장 케이블
(CS) Prodlužovací kabel MediGuide™	(LT) „MediGuide™“ ilginamasis kabelis
(DA) MediGuide™ forlænger kabel	(NL) MediGuide™ verlengsnoer
(DE) MediGuide™ Verlängerungskabel	(NO) MediGuide™ Forlængeselskabel
(EL) Καλώδιο επέκτασης MediGuide™	(PL) Przewód przedłużający MediGuide™
(ES) Cable prolongador MediGuide™	(PT) Cabo de extensão MediGuide™
(ET) MediGuide™ pikenduskaabel	(RU) Удлинительный кабель MediGuide™
(FI) MediGuide™-jatkojohto	(SK) Predĺžovací kábel MediGuide™
(FR) Câble de rallonge MediGuide™	(SR) MediGuide™ produžni kabl
(HU) MediGuide™ hosszabítókábel	(SV) MediGuide™ Förlängningskabel
(IT) Prolunga MediGuide™	(TR) MediGuide™ Uzatma Kablosu
(JA) MediGuide™ 延長ケーブル	(ZH) MediGuide™ 延长电缆

DS2M031

LOT LOT Number:
SAMPLE001



100067050

Use Before:
20XX-XX-XX

Manufacturing Date:
20XX-XX-XX

STERILE EO
 Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.

Do not reuse.

Consult instructions for use.

50°C / 122°F
-5°C / 23°F

Keep away from sunlight.

Keep dry.

Rx **CE** Made in USA
Only 0123



SAP Barcode

GTIN: 05414734XXXXX?

Use Before: 20XX-XX-XX

Lot Number: **LOT** SAMPLE001



(01)05414734XXXXX?(17)YYMMDD(10)1234567

Manufacturer
 St. Jude Medical
 Cardiac Rhythm Management Division
 15900 Valley View Court
 Sylmar, CA 91342 USA
 +1 818 362 6822
 800 722 3774 (US only)

EC REP
 St. Jude Medical AB
 Veddestavägen 19
 SE-175 84 Järfälla
 Sweden
 Tel. +46 8 474 40 00
 Fax. +46 8 760 95 42



MORE CONTROL. LESS RISK.

Final Label Spec: PN

MEDIGUIDE™ EXTENSION CABLE

Use Before: 20XX-XX-XX

Lot Number: DS2M031

GTIN: 05414734XXXXX?



(01)05414734XXXXX?(17)YYMMDD(10)1234567

MEDIGUIDE™ EXTENSION CABLE

Use Before: 20XX-XX-XX

Lot Number: DS2M031

GTIN: 05414734XXXXX?



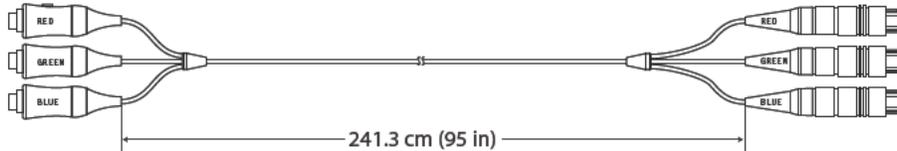
(01)05414734XXXXX?(17)YYMMDD(10)1234567

MEDIGUIDE™ EXTENSION CABLE

- (AR) MediGuide™ كبل الإطالة
- (KO) MediGuide™ 연장 케이블
- (CS) Prodlužovací kabel MediGuide™
- (LT) „MediGuide™“ ilginamasis kabelis
- (DA) MediGuide™ forlænger kabel
- (NL) MediGuide™ verlengsnoer
- (DE) MediGuide™ Verlängerungskabel
- (NO) MediGuide™ Forlængelseskabel
- (EL) Καλώδιο επέκτασης MediGuide™
- (PL) Przewód przedłużający MediGuide™
- (ES) Cable prolongador MediGuide™
- (PT) Cabo de extensão MediGuide™
- (ET) MediGuide™ pikenduskaabel
- (RU) Удлинительный кабель MediGuide™
- (FI) MediGuide™-jatkojohto
- (SK) Predlžovací kábel MediGuide™
- (FR) Câble de rallonge MediGuide™
- (SR) MediGuide™ produžni kabl
- (HU) MediGuide™ hosszabbítókábel
- (SV) MediGuide™ Förlängningskabel
- (IT) Prolunga MediGuide™
- (TR) MediGuide™ Uzatma Kablosu
- (JA) MediGuide™ 延長ケーブル
- (ZH) MediGuide™ 延长电缆

DS2M031

LOT LOT Number:
SAMPLE001



100067050

Use Before:
20XX-XX-XX

Manufacturing Date:
20XX-XX-XX

Pouch Label

STERILE EO

Contents of this package have been ethylene oxide sterilized.



Do not use if package is damaged.



Do not reuse.



Consult instructions for use.

50°C
122°F
-5°C
23°F



Keep away from sunlight.



Keep dry.

R
Only

CE
0123

Made in USA

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

MEDIGUIDE™ EXTENSION CABLE

Use Before: YYY-MM-DD

LOT

SAMPLE1

GTIN: 05414734XXXXX7
(0)05414734XXXXX(17)YMMDD(10)1234567

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

MEDIGUIDE™ EXTENSION CABLE

Use Before: YYY-MM-DD

LOT

SAMPLE1

GTIN: 05414734XXXXX7
(0)05414734XXXXX(17)YMMDD(10)1234567

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

MEDIGUIDE™ EXTENSION CABLE

Use Before: YYY-MM-DD

LOT

SAMPLE1

GTIN: 05414734XXXXX7
(0)05414734XXXXX(17)YMMDD(10)1234567

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

MEDIGUIDE™ EXTENSION CABLE

Use Before: YYY-MM-DD

LOT

SAMPLE1

GTIN: 05414734XXXXX7
(0)05414734XXXXX(17)YMMDD(10)1234567

DS2M031
Lot Number:
SAMPLE1
St. Jude Medical

Manufacturer
St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822
800 722 3774 (US only)

EC REP
St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
Sweden
Tel. +46 8 474 40 00
Fax. +46 8 760 95 42

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Rinal Label Spec. PN

Appendix 24

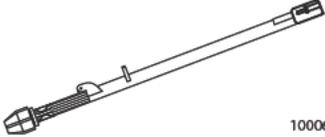
Box Label

Pouch Label

**MEDIGUIDE™
GUIDEWIRE TORQUE CLIP**

(AR) MediGuide™ مشبك ربط عزم دوران سلك التوجيه
 (CS) Torzní svorka pro vodič drát MediGuide™
 (DA) Torque til MediGuide™ guidewire
 (DE) MediGuide™ Torquer für Führungsdraht
 (EL) Κλίπ περιστροφής οδηγού σύρματος MediGuide™
 (ES) Pinza de torque para guía Mediguide™
 (ET) MediGuide™ juhtetraadi pööramisnäpits
 (FI) MediGuide™-ohjainlangan momenttikirstin
 (FR) Pince de torsion pour fil-guide MediGuide™
 (HU) MediGuide™ vezetődrot-forगतó csipesz
 (IT) Clip di torsione guida MediGuide™
 (JA) MediGuide™ ガイドワイヤトルククリップ
 (KO) MediGuide™ 가이드 와이어용 토크 클립
 (LT) „MediGuide™“ kreipiamosios vielos sukamasis spaustukas
 (NL) MediGuide™ torsiëklem voor voerdraad
 (NO) MediGuide™ Guidewire-dreieklips
 (PL) Zacisk obrotowy prowadnika MediGuide™
 (PT) Clip de torção para guias MediGuide™
 (RU) Зажим с ограничением усилия для проводника MediGuide™
 (SK) Torzný klip pre vodič MediGuide™
 (SR) MediGuide™ žica vodič - obrtna spojnica
 (SV) MediGuide™ Åtdragningsklämma för styrtråd
 (TR) MediGuide™ Kılavuz Tel Tork Klipsi
 (ZH) MediGuide™ 导引导丝扭矩夹

DS2M030 **LOT** LOT Number:



100067052

Use Before: Manufacturing Date:

STERILE EO
Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged
 Do not reuse
 Consult applicable Instructions for Use

5°C 23°F 50°C 122°F

Keep away from sunlight
 Keep dry
 R Only
 Made in USA

St. Jude Medical
 Cardiac Rhythm
 Management Division
 15900 Valley View Court
 Sylmar, CA 91342 USA
 +1 818 362 6822
 800 722 3774 (US only)

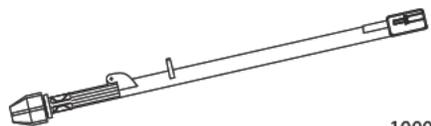
EC REP St. Jude Medical AB
 Veddestavägen 19
 SE-175 84 Järfälla
 Sweden
 Tel: +46 8 474 40 00
 Fax: +46 8 760 95 42

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

**MEDIGUIDE™
GUIDEWIRE TORQUE CLIP**

(AR) MediGuide™ مشبك ربط عزم دوران سلك التوجيه
 (CS) Torzní svorka pro vodič drát MediGuide™
 (DA) Torque til MediGuide™ guidewire
 (DE) MediGuide™ Torquer für Führungsdraht
 (EL) Κλίπ περιστροφής οδηγού σύρματος MediGuide™
 (ES) Pinza de torque para guía Mediguide™
 (ET) MediGuide™ juhtetraadi pööramisnäpits
 (FI) MediGuide™-ohjainlangan momenttikirstin
 (FR) Pince de torsion pour fil-guide MediGuide™
 (HU) MediGuide™ vezetődrot-forगतó csipesz
 (IT) Clip di torsione guida MediGuide™
 (JA) MediGuide™ ガイドワイヤトルククリップ
 (KO) MediGuide™ 가이드 와이어용 토크 클립
 (LT) „MediGuide™“ kreipiamosios vielos sukamasis spaustukas
 (NL) MediGuide™ torsiëklem voor voerdraad
 (NO) MediGuide™ Guidewire-dreieklips
 (PL) Zacisk obrotowy prowadnika MediGuide™
 (PT) Clip de torção para guias MediGuide™
 (RU) Зажим с ограничением усилия для проводника MediGuide™
 (SK) Torzný klip pre vodič MediGuide™
 (SR) MediGuide™ žica vodič - obrtna spojnica
 (SV) MediGuide™ Åtdragningsklämma för styrtråd
 (TR) MediGuide™ Kılavuz Tel Tork Klipsi
 (ZH) MediGuide™ 导引导丝扭矩夹

DS2M030 **LOT** LOT Number:



100067052

Use Before: Manufacturing Date:

STERILE EO
Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.
 Do not reuse.
 Consult applicable Instructions for Use.

-5°C 23°F 50°C 122°F

Keep away from sunlight.
 Keep dry.
 R Only
 Made in USA

St. Jude Medical
 Cardiac Rhythm
 Management Division
 15900 Valley View Court
 Sylmar, CA 91342 USA
 +1 818 362 6822
 800 722 3774 (US only)

EC REP St. Jude Medical AB
 Veddestavägen 19
 SE-175 84 Järfälla
 Sweden
 Tel: +46 8 474 40 00
 Fax: +46 8 760 95 42

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Appendix 25

Box Label

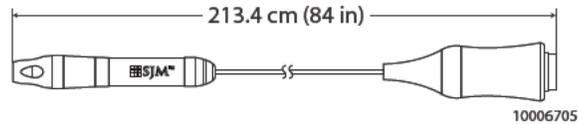
MEDIGUIDE™ GUIDEWIRE CONNECTOR

Electrical Connection for MediGuide Enabled™ Guidewire

- | | |
|--|---|
| (AR) توصيل كوربائي لسلك التوجيه
MediGuide Enabled™ | (KO) MediGuide Enabled™ 가이드 와이어
연결 케이블 |
| (CS) Elektrická přípojka pro vodič
drát MediGuide Enabled™ | (LT) Elektros jungtis, skirta „MediGuide
Enabled™“ kreiplamajai vielai |
| (DA) Elektrisk tilslutning til MediGuide
Enabled™ guidewire | (NL) Elektrische aansluiting voor
MediGuide Enabled™ voerdraad |
| (DE) Elektrischer Anschluss für
MediGuide Enabled™ Führungsdraht | (NO) Elektrisk forbindelse for MediGuide
Enabled™ Guidewire |
| (EL) Ηλεκτρική σύνδεση για οδηγό σύρμα
MediGuide Enabled™ | (PL) Połączenie elektryczne przewodnika
MediGuide Enabled™ |
| (ES) Conexión eléctrica para guía
MediGuide Enabled™ | (PT) Ligação eléctrica para guias
MediGuide Enabled™ |
| (ET) Elektriühendus MediGuide
Enabled™ juhtetraadile | (RU) Электрическое подключение
проводника MediGuide Enabled™ |
| (FI) MediGuide Enabled™ -ohjainlangan
sähköliitäntä | (SK) Elektrická prípojka pre vodič
MediGuide Enabled™ |
| (FR) Raccordement électrique pour
fil-guide MediGuide Enabled™ | (SR) Električna veza za MediGuide™
vodilč žicu |
| (HU) Elektromos csatlakoztatás MediGuide
Enabled™ típusú vezetődótokhoz | (SV) Elektrisk anslutning för MediGuide
Enabled™ Styrtråd |
| (IT) Collegamento elettrico per guida
MediGuide Enabled™ | (TR) MediGuide Enabled™ Kılavuz Tel İçin
Elektrik Bağlantısı |
| (JA) MediGuide Enabled™ ガイド
ワイヤとの電気的接続 | (ZH) MediGuide Enabled™
导引导丝的电气连接 |

DS2M032

LOT LOT Number:



Use Before:

Manufacturing Date:

STERILE EO Contents of this package have been ethylene oxide sterilized. Do not use if package is damaged. Do not reuse. Consult applicable instructions for use.

50°C 122°F
-5°C 23°F
Keep away from sunlight. Keep dry. **Rx Only** Made in USA

Manufacturer
St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822
800 722 3774 (US only)

EC REP
St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
Sweden
Tel. +46 8 474 40 00
Fax. +46 8 760 95 42

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Box Label

(91)ZFIN#(92)MODEL#(17)YYMMDD(10)SAMPLE001(30)OTY
 For Internal Purposes Only
 MEDIGUIDE™ GUIDEWIRE CONNECTOR
 Electrical Connection for MediGuide Enabled™ Guidewire
 DS2M032

MEDIGUIDE™

GUIDEWIRE CONNECTOR

Electrical Connection for MediGuide Enabled™ Guidewire

AR توصيل كوربائي لسلك التوجيه
MediGuide Enabled™

CS Elektrická přípojka pro vodící drát MediGuide Enabled™

DA Elektrisk tilslutning til MediGuide Enabled™ guidewire

DE Elektrischer Anschluss für MediGuide Enabled™ Führungsdraht

EL Ηλεκτρική σύνδεση για οδηγό σύρμα MediGuide Enabled™

ES Conexión eléctrica para guía MediGuide Enabled™

ET Elektriühendus MediGuide Enabled™ juhtetraadile

FI MediGuide Enabled™ -ohjainlangan sähköliitäntä

FR Raccordement électrique pour fil-guîde MediGuide Enabled™

HU Elektromos csatlakoztatás MediGuide Enabled™ típusú vezetôdrôtokhoz

IT Collegamento elettrico per guida MediGuide Enabled™

JA MediGuide Enabled™ ガイドワイヤとの電気的接続

KO MediGuide Enabled™ 가이드 와이어 연결 케이블

LT Elektros jungtis, skirta „MediGuide Enabled™“ kreipliamajai vielai

NL Elektrische aansluiting voor MediGuide Enabled™ voerdraad

NO Elektrisk forbindelse for MediGuide Enabled™ Guidewire

PL Połączenie elektryczne przewodnika MediGuide Enabled™

PT Ligação eléctrica para guias MediGuide Enabled™

RU Электрическое подключение проводника MediGuide Enabled™

SK Elektrická prípojka pre vodíč MediGuide Enabled™

SR Električna veza za MediGuide™ vodíč žicu

SV Elektrisk anslutning för MediGuide Enabled™ Styrtråd

TR MediGuide Enabled™ Kılavuz Tel için Elektrik Bağlantısı

ZH MediGuide Enabled™ 导引导丝的电连接

DS2M032

LOT LOT Number:
SAMPLE1

213.4 cm (84 in)

100067051

Use Before:
20XX-XX-XX

Manufacturing Date:
20XX-XX-XX

STERILE EO
 Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.

Do not reuse.

Consult applicable instructions for use.

50°C / 122°F
 -5°C / 23°F

Keep away from sunlight.

Keep dry.

Rx **CE** Made in USA
 Only 0123

SAP Barcode

GTIN: 05414734XXXXX?

Use Before:
20XX-XX-XX

LOT Lot Number:
SAMPLE1

(01)05414734XXXXX?(17)YYMMDD(10)1234567

Manufacturer
 St. Jude Medical
 Cardiac Rhythm
 Management Division
 15900 Valley View Court
 Sylmar, CA 91342 USA
 +1 818 362 6822
 800 722 3774 (US only)

EC REP

St. Jude Medical AB
 Veddestavägen 19
 SE-175 84 Järfälla
 Sweden
 Tel. +46 8 474 40 00
 Fax. +46 8 760 95 42

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Final Label Spec: PH

MEDIGUIDE™ GUIDEWIRE CONNECTOR
 Electrical Connection for MediGuide Enabled™ Guidewire
 GTIN: 05414734XXXXX?

Use Before:
20XX-XX-XX

LOT Lot Number:
SAMPLE1

(01)05414734XXXXX?(17)YYMMDD(10)1234567

MEDIGUIDE™ GUIDEWIRE CONNECTOR
 Electrical Connection for MediGuide Enabled™ Guidewire
 GTIN: 05414734XXXXX?

Use Before:
20XX-XX-XX

LOT Lot Number:
SAMPLE1

(01)05414734XXXXX?(17)YYMMDD(10)1234567

60018426

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

Revision A

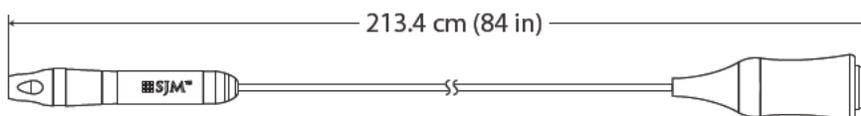
MEDIGUIDE™ GUIDEWIRE CONNECTOR

Electrical Connection for MediGuide Enabled™ Guidewire

- (AR) MediGuide Enabled™ توصيل كورياتي لسلك التوجيه
- (CS) Elektrická přípojka pro vodič drát MediGuide Enabled™
- (DA) Elektrisk tilslutning til MediGuide Enabled™ guidewire
- (DE) Elektrischer Anschluss für MediGuide Enabled™ Führungsdraht
- (EL) Ηλεκτρική σύνδεση για οδηγό σύρμα MediGuide Enabled™
- (ES) Conexión eléctrica para guía MediGuide Enabled™
- (ET) Elektriühendus MediGuide Enabled™ juhtetraadile
- (FI) MediGuide Enabled™ -ohjainlangan sähköliitäntä
- (FR) Raccordement électrique pour fil-guide MediGuide Enabled™
- (HU) Elektromos csatlakoztatás MediGuide Enabled™ típusú vezetődrótokhoz
- (IT) Collegamento elettrico per guida MediGuide Enabled™
- (JA) MediGuide Enabled™ ガイド ワイヤとの電気的接続
- (KO) MediGuide Enabled™ 가이드 와이어 연결 케이블
- (LT) Elektros jungtis, skirta „MediGuide Enabled™“ kreipiamajai vielai
- (NL) Elektrische aansluiting voor MediGuide Enabled™ voerdraad
- (NO) Elektrisk forbindelse for MediGuide Enabled™ Guidewire
- (PL) Połączenie elektryczne przewodnika MediGuide Enabled™
- (PT) Ligaçao eléctrica para guias MediGuide Enabled™
- (RU) Электрическое подключение проводника MediGuide Enabled™
- (SK) Elektrická prípojka pre vodič MediGuide Enabled™
- (SR) Električna veza za MediGuide™ vodič žicu
- (SV) Elektrisk anslutning för MediGuide Enabled™ Styrtråd
- (TR) MediGuide Enabled™ Kilavuz Tel için Elektrik Bağlantısı
- (ZH) MediGuide Enabled™ 导引导丝的电气连接

DS2M032

LOT LOT Number:
SAMPLE001



100067051

Use Before:
20XX-XX-XX

Manufacturing Date:
20XX-XX-XX

STERILE EO

Contents of this package have been ethylene oxide sterilized.

Do not use if package is damaged.

Do not reuse.

Consult applicable instructions for use.

50°C
122°F
-5°C
23°F

Keep away from sunlight.

Keep dry.

R
Only

CE
0123

Made in USA

Pouch Label

DS2M032 Lot Number: SAMPLE001 St. Jude Medical

MEDIGUIDE™ GUIDEWIRE CONNECTOR
Electrical Connection for MediGuide Enabled™ Guidewire
GTIN: 05414734XXXXX7
Use Before: YYYY-MM-DD
(0)J05414734XXXXX(17)YMMDD(10)1234567

DS2M032 Lot Number: SAMPLE001 St. Jude Medical

MEDIGUIDE™ GUIDEWIRE CONNECTOR
Electrical Connection for MediGuide Enabled™ Guidewire
GTIN: 05414734XXXXX7
Use Before: YYYY-MM-DD
(0)J05414734XXXXX(17)YMMDD(10)1234567

DS2M032 Lot Number: SAMPLE001 St. Jude Medical

MEDIGUIDE™ GUIDEWIRE CONNECTOR
Electrical Connection for MediGuide Enabled™ Guidewire
GTIN: 05414734XXXXX7
Use Before: YYYY-MM-DD
(0)J05414734XXXXX(17)YMMDD(10)1234567

DS2M032 Lot Number: SAMPLE001 St. Jude Medical

MEDIGUIDE™ GUIDEWIRE CONNECTOR
Electrical Connection for MediGuide Enabled™ Guidewire
GTIN: 05414734XXXXX7
Use Before: YYYY-MM-DD
(0)J05414734XXXXX(17)YMMDD(10)1234567

DS2M032 Lot Number: SAMPLE001 St. Jude Medical

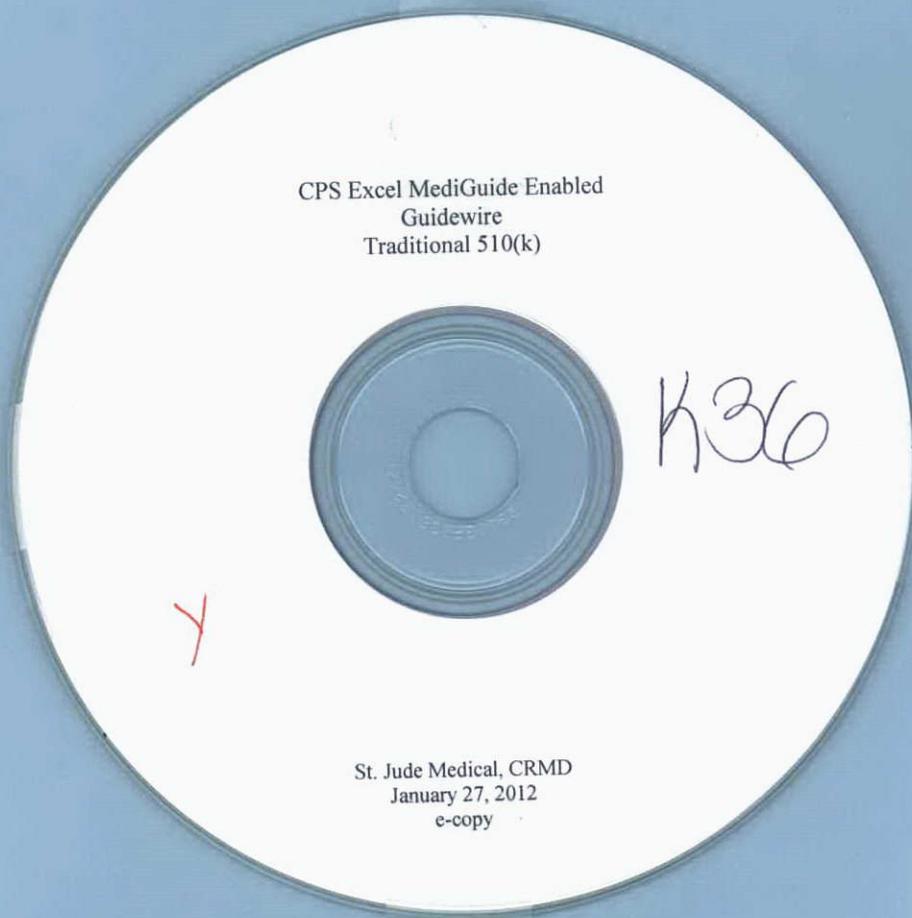
MEDIGUIDE™ GUIDEWIRE CONNECTOR
Electrical Connection for MediGuide Enabled™ Guidewire
GTIN: 05414734XXXXX7
Use Before: YYYY-MM-DD
(0)J05414734XXXXX(17)YMMDD(10)1234567

Manufacturer
St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822
800 722 3774 (US only)

EC REP St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
Sweden
Tel. +46 8 474 40 00
Fax. +46 8 760 95 42

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Rinal Label Spec. PN



CPS Excel MediGuide Enabled
Guidewire
Traditional 510(k)

K36

y

St. Jude Medical, CRMD
January 27, 2012
e-copy



COVER SHEET MEMORANDUM

From: Reviewer Name Frank Lacy
Subject: 510(k) Number K120298/S1
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision **(SE)** SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source? adult

All Pediatric Patients age <= 21

Neonate/Newborn (Birth to 28 days)

Infant (29 days - < 2 years old)

Child (2 years - < 12 years old)

Adolescent (12 years - < 18 years old)

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC. ~~X~~

Regulation Number

21 CFR 870.1330

Class*

II (two)

Product Code

74 DQX

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

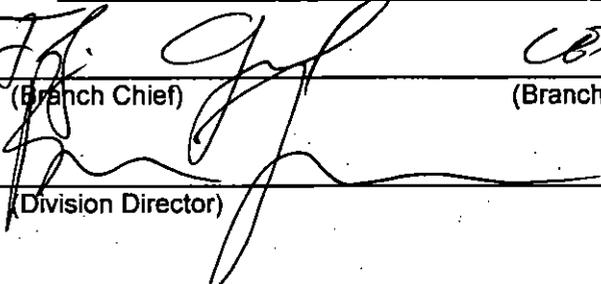
Review:


(Branch Chief)

CE7B
(Branch Code)

5/8/12
(Date)

Final Review:


(Division Director)

5/8/12
(Date)

Aguel, Felipe

From: Lacy, Frank
Sent: Monday, May 07, 2012 6:21 PM
To: Aguel, Felipe
Subject: K120298

Attachments: K120298arevisednewrevtemplate.doc

Hello Felipe,

Please find attached my memo for the St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire and accessories. Please accept this as my official copy for the record. The additional information concerns are outlined in the Contact Section of the memorandum at the end of the document. I am also forwarding a copy of the e-mail and my response to the company for the request for additional information to go along with this documentation.



K120298arevis
newrevtemplate

Thanks,
Frank

**Premarket Notification [510(k)] Review
Traditional**

 K120298/S1

Date: May 7, 2012
To: The Record
From: Frank Lacy

Office: ODE
Division: DCD

510(k) Holder: St. Jude Medical
Device Name: CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Contact: Colleen Canan
Phone: (818) 493-2960
Fax: (818) 493-3615
Email: ccanan@sjm.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce a new CPS Excel™ MediGuide Enabled™ Guidewire and accessories into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

The CPS Excel guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The design of the CPS Excel, MediGuide Enabled guidewire is based on the design of the commercially available CPS Courier guidewire (predicate) with the accommodation of a MediGuide sensor. The guidewire contains a magnetic sensor allowing it to be tracked using the MediGuide System.

Like its predicate device, the CPS Excel MediGuide Enabled guidewire is intended for use in the coronary and peripheral vasculature. The diameter of the guidewire is sized to allow it to pass through the lumen of a LV pacing lead. The MediGuide enabled guidewire has three distinct regions: proximal connector region, middle region (guidewire body), and the distal tip region.

Proximal Connector Region

Electronic interface/connection of the MediGuide guidewire is accomplished at the proximal end of the guidewire. The proximal end contains two (b)(4) rings which are separated and electrically isolated from one another by polymeric rings. The (b)(4) rings have a diameter similar to that of the guidewire body thus allowing passage through the lumen of a pacing lead. The (b)(4) rings and polymeric rings are supported by a core wire which is bonded to the guidewire body. The sensor cabling runs alongside the core wire and are connected to the (b)(4) rings.

Middle Region

The guidewire body consists of a hollow (b)(4) tube that provides a lumen for passage of the sensor conductor wires (cables). The (b)(4) tube also contains a (b)(4) core wire (safety wire) which is securely attached to both the distal and proximal ends of the guidewire. The guidewire is coated with (b)(4) to ensure sufficient lubricity to the (b)(4) wire. The predicate CPS Courier guidewire is also coated with (b)(4).

Distal tip region

The distal most component of the Excel guidewire contains the MediGuide Sensor. The sensor is securely attached to the guidewire via the core wire. The MediGuide sensor consists of copper wire coiled around a metal core and connected to a sensor cable. Immediately proximal of the MediGuide sensor is a (b)(4) coil (Pt) which provides radiopacity for tracking on live fluoroscopy. The distal portion of the (b)(4) tube is cut in a helical pattern to provide a flexible tip. The pitch of the cut varies to provide varying degrees of stiffness. The stiffness of the helical cut section increases from proximal to distal, like its predicate wire (CPS Courier). The distal portion of the (b)(4) tube is also ground down to a smaller diameter than the guidewire body. The smaller diameter provides less stiffness and also allows space for a soft polymer (b)(4) coating. The soft polymer coating is identical to the predicate wire and encapsulates the entire distal region of the guidewire including the MediGuide Sensor. The (b)(4) coating is then coated with a hydrophilic coating to provide lubricity.

Description of Accessories:

Each guidewire kit contains one guidewire and pouched J-straightener and torque tool. The guidewire is packaged in a spiral dispenser with a luer adapter on the outer end. The dispenser which is retained in its shape with (b)(4) clips and has one anti-migration device which grips one point of the wire to prevent its movement within the hoop during transportation. The polymer coated distal tip of the guidewire lies along the outside diameter of the dispenser nearest the luer adapter. Each dispenser assembly and pouched J-straightener and torque tool are placed in an outer pouch and sealed.

The MediGuide™ extension cable accessory is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire via the MediGuide guidewire connector to the MediGuide™ System.

The purpose of the cable is to provide the implanting physician with a sterile connection for the desired delivery tool. The MediGuide Enabled delivery tool needs to be connected to the MediGuide Cath Connect interface box to be able to track the tool on the MediGuide system. The MediGuide extension cable is used to bridge the gap between the MediGuide Cath Connect interface box and the MediGuide Enabled delivery tool. Thus the MediGuide extension cables creates an extra layer of protection by allowing the physician to keep the MediGuide Enabled delivery tool completely in the sterile field and offering the possibility to connect, disconnect and change delivery tools without having to extend beyond the sterile field. The length of the extension cables is sufficient enough to lay them over the sterile drapes without pulling either ends.

The MediGuide extension cable consists of three connectors on each side. The three connectors

allow connections of up to three MediGuide Enabled delivery tools to the MediGuide system. The cables that connect to the MediGuide system consists of standard ODU connectors that are plugged into the MediGuide system's Cath Connect box. The other end of the cables is comprised of standard Redel connectors that are magnetically shielded and are compatible with the MediGuide Enabled delivery tools. Trifurcated cables on both ends are color coded respectively to identify correct device connection on both ends.

MEDIGUIDE GUIDEWIRE CONNECTOR

The MediGuide guidewire connector accessory is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire to the MediGuide extension cable. The guidewire is inserted into the connector until it bottoms out. Once the guidewire cannot be pushed any further, the nut on the connector end is tightened to fixate the guidewire in the connector. Inside the molded connector housing is a printed circuit board (PCB) which is wrapped with magnetic shielding. The PCB has contact slots that connect with the electrical contacts of the guidewire for electrical functionality. The other end of the MediGuide guidewire connector is a standard Redel connector that is magnetically shielded and connects to the MediGuide Extension Cable.

MEDIGUIDE GUIDEWIRE TORQUE CLIP

The MediGuide guidewire torque clip is an accessory that is used to torque the guidewire. It is also used to secure the LV pacing lead and guidewire together. Locking the tip of the CPS Excel MediGuide Enabled guidewire with the tip of a LV pacing lead enables real-time tip visualization and navigation of the LV pacing lead that does not contain a MediGuide sensor.

The guidewire clip has two (b)(4) molded arms attached by a hinge that allows the clip to pivot over the guidewire path. These arms are defined as the clip body and the torque body. The end of the clip body that is opposite of the hinge pin includes two opposing clip arms which can be pushed so as to insert or release the lead connector. A graphic of a lead connector is pad printed on one of the clip arms to guide the user in locating the lead connector within the clip arms. The end of the torque body opposite of the hinge pin contains a tightening screen that is used to secure the guidewire to the torque clip.

The MediGuide Enabled guidewire is passed through the torque clip and the pacing lead. The tip of the guidewire is then matched with the tip of the pacing lead and the nut on the clip is tightened to lock the two together. When inserted inside the anatomy, the implanting physician can now visualize the tip of the pacing lead by using the guidewire sensor locked at its tip. To advance the guidewire past the lead tip, the implanting physician would compress the finger tabs to remove the clip from the lead and advance the clip towards the lead connector. Similar to a typical over-the-wire technique, the physician can now safely track the lead over the wire by holding the guidewire in position and advancing the lead over the wire until it reaches the distal end of the wire. To re-position the guidewire with the tip of the lead, reconnect the clip to the lead connector. Thus the MediGuide guidewire torque clip gives the physician the ability to visualize the lead tip while tracking the lead safely over the wire at the same time.

The manufacturer has indicated that the device is the St. Jude Medical CPS Excel™, MediGuide Enabled™ guidewire is a MediGuide enabled guidewire with a hydrophilic coating. The CPS Excel, MediGuide Enabled guidewire contains a magnetic sensor allowing it to be visualized using the MediGuide system.

Concise Description of the Device-CPS Excel MediGuide Enabled Guidewire

The CPS Excel, MediGuide guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The guidewire comes in three unique base models distinguished by their unique distal flexibility profiles. Each base model comes with an angled distal tip. The guidewire contains a magnetic sensor allowing it to be tracked using the MediGuide System.

Concise Description of the Accessory- MediGuide Extension Cable

The St Jude Medical MediGuide extension cable is a flexible, insulated cable constructed of metal and plastic materials. This cable is compatible for single use only.

Concise Description of the Accessory- MediGuide Guidewire Connector

The MediGuide guidewire connector is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire to the MediGuide extension cable.

Concise Description of the Accessory- MediGuide Guidewire Torque Clip

The MediGuide torque clip is an accessory that is used to torque the guidewire. It is also used to secure the LV pacing lead and guidewire together. Locking the tip of the CPS Excel MediGuide Enabled guidewire with the tip of a LV pacing lead enables real-time tip visualization and navigation of the LV pacing lead that does not contain a MediGuide sensor.

Models

The CPS Excel MediGuide Enabled guidewire consists of guidewires available in different stiffness profiles. The CPS Excel MediGuide Enabled guidewires come in three unique base models distinguished by their unique distal flexibility profiles. Each base model comes with an angled distal tip. The guidewires all come in 195 cm lengths.

Model Number Description

- DS2M027: MediGuide guidewire- Soft (S)
- DS2M028: MediGuide guidewire- Medium (M)
- DS2M029: MediGuide guidewire- Extra Firm (XF)

IV. Indications for Use

According to the manufacturer, "The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

V. Predicate Device Comparison

see Comparison Table below

Table : Comparison Table

	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) K073082	MediGuide Measurement Catheter (GMC) (Predicate Device) K091780
Product Code	DQY	DQX	DQO
Regulation	870.1330	870.1330	870.1200

<p>Indications for Use</p>	<p>The St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.</p>	<p>The CPS Courier Guidewires are intended for use in coronary and peripheral vasculature.</p>	<p>The GMC device is a gMPS enabled intravascular catheter intended for the diagnostic evaluation of the coronary vasculature in patients who are candidates for coronary angiography and/or Percutaneous Coronary Intervention (PCI)</p> <p>The GMC is used with compatible</p>
	<p>St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)</p>	<p>St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) K073082</p>	<p>MediGuide Measurement Catheter (GMC) (Predicate Device) K091780</p>
			<p>gMPS system to enable real-time tip positioning and navigation, quantitative reconstruction, qualitative 3D foreshortening indications, and landmarking The System is indicated for use as an adjunct to fluoroscopy.</p>

<p>Device Description</p>	<p>The CPS Excel MediGuide Enabled guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The key design features are:</p> <ul style="list-style-type: none"> • (b)(4) hypo tube • (b)(4) coated SS • (b)(4) jacketed tip • Hydrophilically coated tip • Copper sensor cable • Copper sensor • Proximal (b)(4) 	<p>The St Jude Medical CPS Courier Guidewire is a 0.014" PTFE coated (b)(4) core wire, the distal end of which is reduced in diameter. The key design features are:</p> <ul style="list-style-type: none"> • (b)(4) core wire • (b)(4) coated SS • (b)(4) jacketed tip • Hydrophilically coated tip 	<p>3.5F catheter with a maximal shaft Inner diameter of 1.15 mm, a tapered tip Inner diameter of 0.58 mm, and a usable length of 135 cm</p>
	<p>St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)</p>	<p>St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) K073082</p>	<p>MediGuide Measurement Catheter (GMC) (Predicate Device) K091780</p>
	<ul style="list-style-type: none"> • (b)(4) conductor rings • (b)(4) spacers 		
<p>OD</p>	<p>0.014"</p>	<p>Same as subject device</p>	<p>3.5 F</p>
<p>Working Length</p>	<p>195 cm</p>	<p>Same as subject device</p>	<p>135 cm</p>
<p>No. of models</p>	<p>3</p>	<p>10</p>	<p>1</p>
<p>Coating</p>	<p>Hydrophilic and (b)(4)</p>	<p>Same as subject device</p>	<p>(b)(4)</p>

Distal End Stiffness	Soft, Medium, & Extra Firm	Extra Soft, Soft, Medium, Firm & Extra Firm	NA
Tip Shape	J-tip	Straight and J-tip	NA
Compatibility with Navigation System	Yes	NA	Same as subject device
Measures Enabled via the Computerized System while working in conjunction with device	Real-time tip positioning and navigation	NA	Same as subject device

	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) K073082	MediGuide Measurement Catheter (GMC) (Predicate Device) K091780
Sterility	Supplied Sterile	Same as subject device	Same as subject device
Tissue Contacting materials- Ground Hypo Tube	Top Coat: (b)(4) (b)(4)	Same as subject device	NA
Tissue Contacting Materials- Coating	Hydrophilic coating (b)(4)	Same as subject device	NA

Tissue Contacting Materials- Polymer jacket	(b)(4)	Same as subject device	NA
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The subject device incorporates the following modifications to the predicate device:

Table of Modifications

Design Feature	CPS Excel, MediGuide Enabled	CPS Courier	Reason for change
Guidewire body	Hypo tube	Solid core wire	Hypo tube (lumen) needed to route the sensor cable
Proximal end	(b)(4) conductor rings	No conductor rings	Conductor rings are required to connect to the sensor cable and then make a connection to the navigation system
Sensor	Encapsulated sensor at the distal end	No sensor	Sensor required to allow for tracking with a navigation system.

All technological characteristics of CPS Excel MediGuide Enabled guidewire are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the proposed device and the predicate devices, performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device.

Predicate Device(s):

**K073082; CPS Courier Guidewire; St. Jude Medical
K091780; MediGuide Guided Measurement Catheter; MediGuide**

Both the CPS Excel MediGuide Enabled guidewire and the predicate CPS Courier guidewire facilitate navigation within the coronary and peripheral vasculature.

The only technology utilized from the MediGuide Measurement Catheter (GMC) is the passive gMPS sensor set which is incorporated internally within the tip of the MediGuide Enabled guidewire to be located or read by the MediGuide gMPS System II (gMPS II) (K102905).

VI. Labeling

The sponsor provides labeling that appears to be appropriate for this Rx device. Details on how to use the MediGuide guidewire torque clip can be found in the CPS Excel MediGuide Enabled guidewire Instructions for Use (IFU) manual. This is acceptable to this reviewer.

VII. Sterilization/Shelf Life/Reuse

The proposed device is provided sterile. The CPS Excel MediGuide Enabled guidewire, accessory extension cable, and accessory guidewire connector are sterilized using (b)(4). The Sterility Assurance is 10⁻⁶. This is acceptable to this reviewer. The packaging for the CPS Excel MediGuide Enabled guidewire and accessory MediGuide extension cable, guidewire torque clip and guidewire connector are designed to protect the devices from damage and prevent contamination during storage, shipping, handling and introduction to the sterile field. The packaging designs, materials and labeling are compatible with (b) sterilization and capable of providing adequate sterile barrier for the anticipated shelf life of the device. This is acceptable to this reviewer.

SJM is currently requesting a shelf life of 1 year. The testing performed demonstrates the stability and functionality of the CPS Excel MediGuide Enabled guidewire and accessory MediGuide extension cable, guidewire connector and guidewire torque clip. The one year accelerated aging test report simulating one year shelf life storage for the CPS Excel MediGuide Enabled guidewire is provided and the accessory MediGuide extension cable is provided. The accessory guidewire connector is provided and the accessory guidewire torque clip is provided. These have been reviewed and found to be acceptable by this reviewer.

VIII. Biocompatibility

According to ANSI/AAMI/ISO 10993-1, "Biological Evaluation of Medical Devices", the fluid path contact components associated with the CPS Excel MediGuide Enabled guidewire is classified as Externally Communicating Device, Circulating Blood with Limited Contact Duration (< 24 hours). The MediGuide guidewire torque clip is a product contact device with no direct patient contact. The biocompatibility testing conducted for the guidewire torque clip addresses only the transfer of potential leachables from the guidewire torque clip to the guidewire and ultimately to the patient during use of the guidewire.

Biocompatibility Table

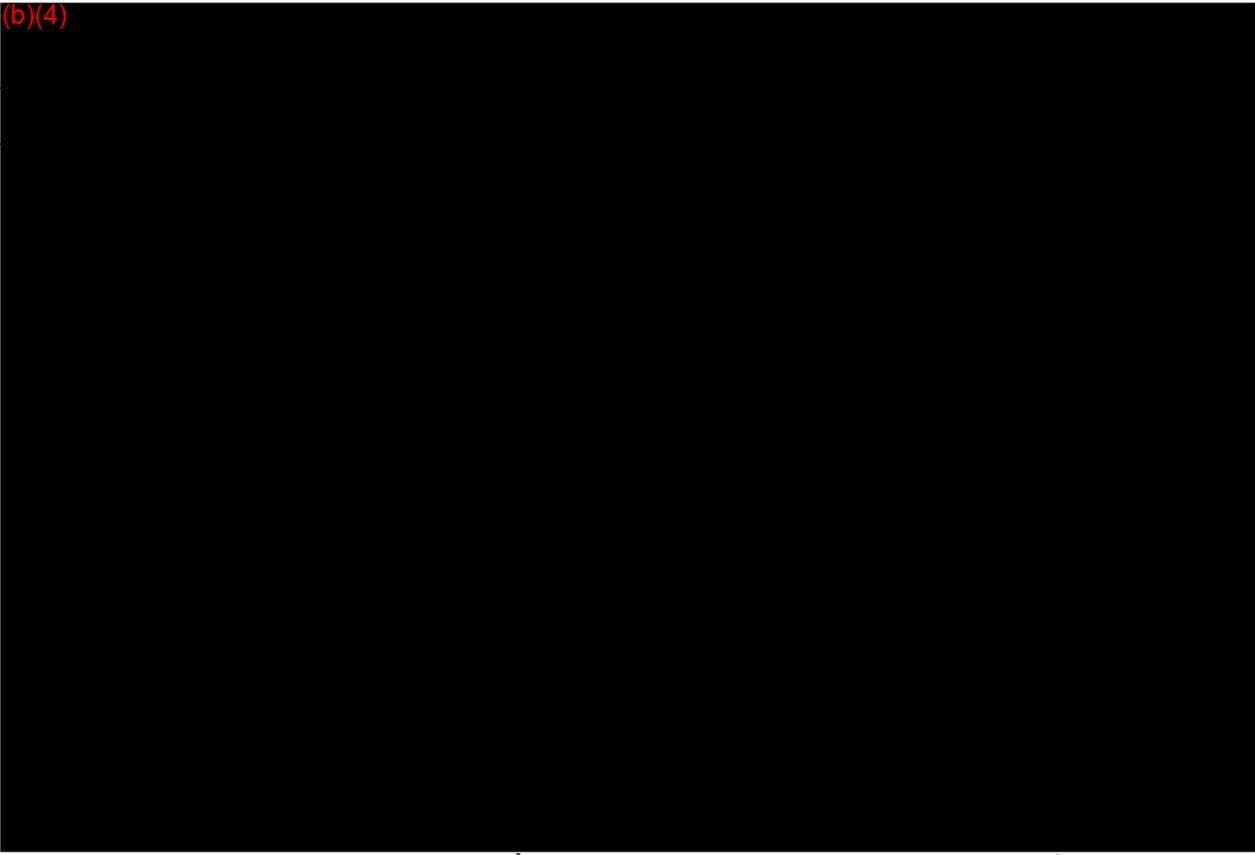
St. Jude Medical CPS Excel MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029	
Part name	Raw material
Ground Hypo Tube	Top Coat: (b) (b)(4)
Coating	Hydrophilic Coating (b)(4)
Polymer Jacket	

A summary of test results are provided in the Table below.

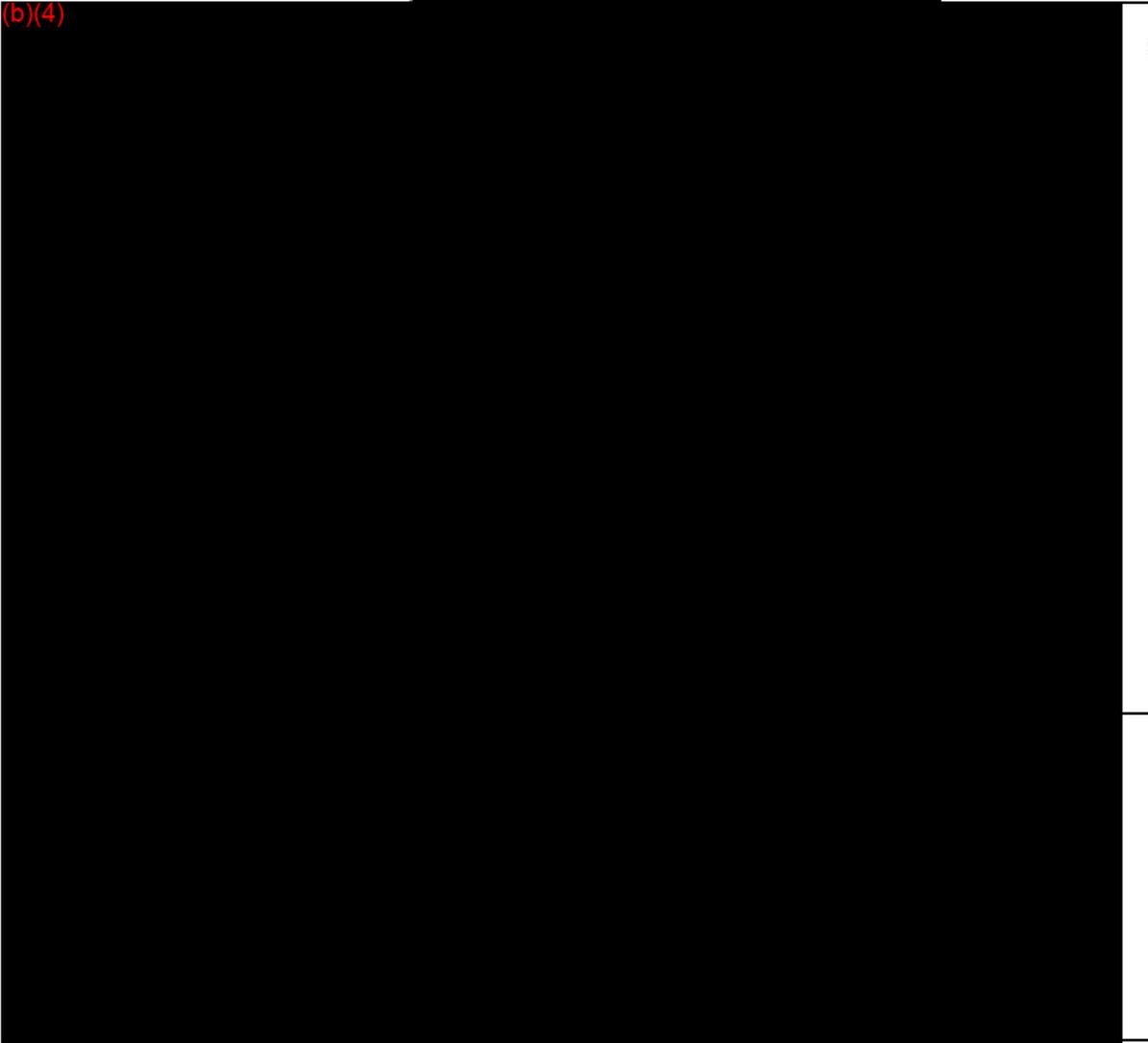
Summary of Biocompatible Testing Table

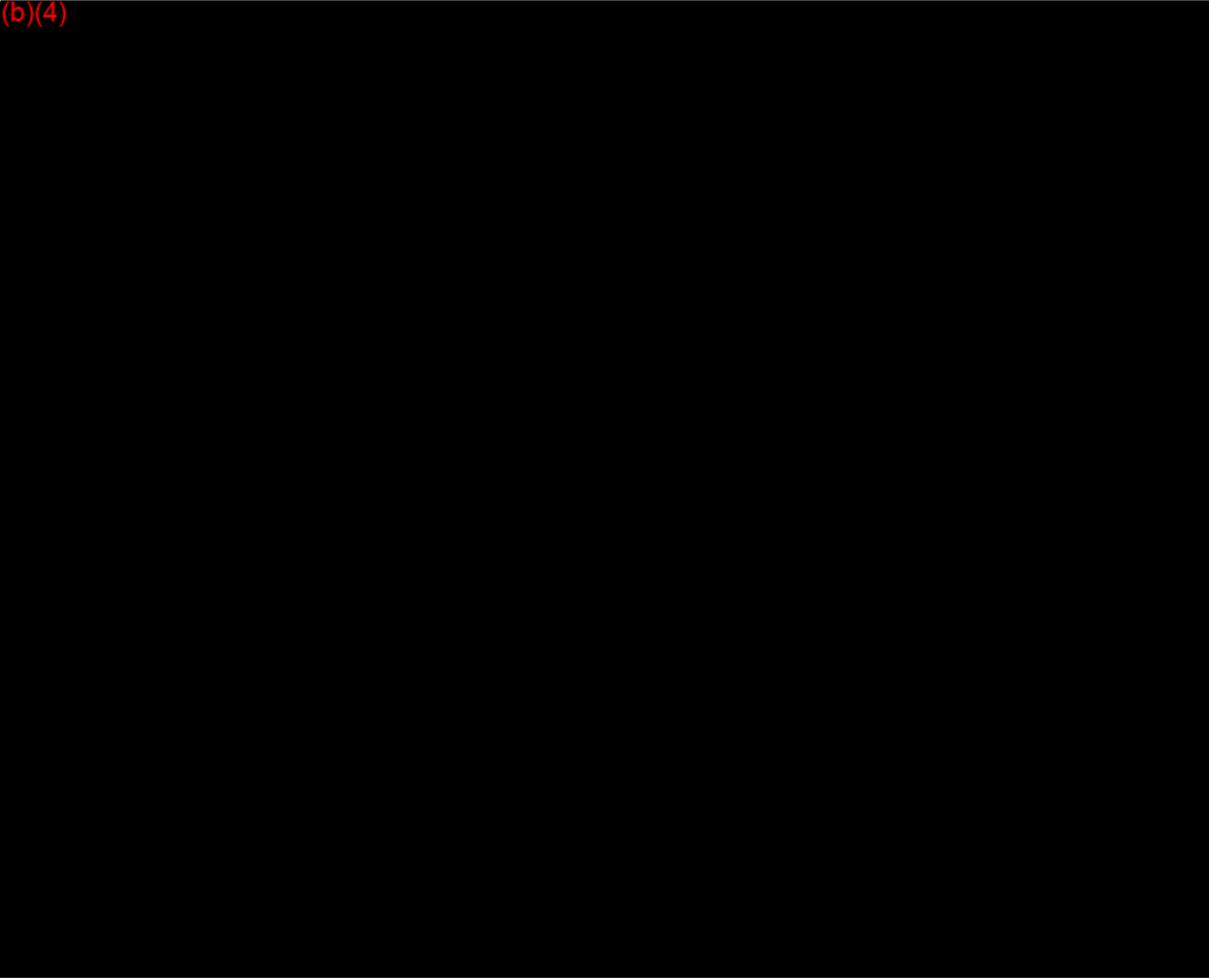
Biocompatibility Testing		
Test Description	Acceptance Criteria	Result
(b)(4)		

(b)(4)



(b)(4)





The Biocompatibility testing report of the CPS Excel MediGuide Enabled guidewire is provided. Biocompatibility testing was also conducted on the accessory guidewire torque clip and provided. The accessory MediGuide extension cable and guidewire connector are non patient contacting therefore no biocompatibility testing were required for these accessories.

The test reports are provided and complete. This is acceptable to this reviewer.

IX. Software

N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

XI. Performance Testing – Bench

Design Requirements and Performance Specifications

The Table below lists the design requirements and performance specifications for the CPS Excel MediGuide Enabled guidewire and the accessory extension cable, guidewire torque clip and guidewire connector.

Table: Design Requirements and Performance Specifications	
Parameter	Requirement/Specification
Dimensional:	<ul style="list-style-type: none"> The guidewire is to be 0.0145” in diameter or less Each guidewire shall be 195 ± 3 cm in length.
Functional Requirement: Guidewire	<ul style="list-style-type: none"> Each guidewire shall have a distal coating consisting of (b)(4) blended with (b) to provide radiopacity. The distal tip coating of the guidewire shall be radiopaque. The midsection of each guidewire shall have a (b) coating. The Guidewire (b)(4) coating must withstand 1 insertion and withdrawal into a lead while the lead is placed in labyrinth path. The distal tip of the guidewire shall incorporate a coil for Radiopacity. The coil shall be (b)(4). The distal tip will contain a MediGuide sensor. The MediGuide sensor will be contained within the (b)(4) coating and will be attached to the guidewire via the core wire. The polymer coating will be over-coated with a hydrophilic coating. Each guidewire shall not exhibit any polymer coating damage when inserted into a device 10 times within a vessel model. Metallic components of the guidewire shall show no signs of corrosion that affects functional performance or biocompatibility test results when tested per the corrosion resistance test method described in annex B of ISO 11070.
Structural Requirements	

<p>Structural Requirements Guidewire</p>	<ul style="list-style-type: none"> • The core wire acts as the safety wire for the device thus the core wire and the distal bond joint must withstand 0.5 lbs of axial load. • The guidewire shall withstand a minimum of 5 turns without failure while a 0.03 lbf tensile force is applied. • The guidewire must track thru a lead when it is placed into a vessel model. • The guidewire must pass the (b)(4) Test described in ISO (b)(4) • The guidewire must pass the (b)(4) Test described in ISO (b)(4)
<p>Electrical Requirements</p>	
<p>Electrical Requirements Guidewire</p>	<ul style="list-style-type: none"> • The proximal section of each guidewire will have electrical connections that provide compatibility with the Guidewire Connector handle/interface cable. The proximal portion

	<p>of the guide wire must withstand five (5) insertion withdrawals into the Guidewire Connector Handle without physical damage or loss of electrical integrity.</p> <ul style="list-style-type: none"> • Electrical Integrity: The electrical resistance across the two conductor rings should be between 200 and 300 ohms. The resistance from each of the conductor rings to the exposed metal on the guidewire body must be greater than 3 mega-ohm. • The electrical integrity must be maintained when the guidewire is inserted into a device 10 times within a vessel model. • The guidewire must maintain its electrical integrity when soaked in 37° C (± 2°C) saline for a minimum of 2 hours. • The polarity of the sensor shall be consistently wired to the connector. The sensor coil supply (inner) wire shall be wired to proximal connector ring and the sensor coil return (outer) wire shall be wired to
<p>Sensor Accuracy Requirements Guidewire</p>	<ul style="list-style-type: none"> • When tested under non-unidirectional AC magnetic field of 10uT, generated from 9 concurrent coils at 10-14kHz, emitted from the MediGuide system MTA (magnetic transmitter assembly) magnetic field vector with the guidewire connector placed 30 cm radially from the edge of the MTA the following is required: • Average static positional accuracy error shall be less than 0.5mm with a maximum standard deviation of 0.3mm.
<p>Torque Tool Requirement</p>	<ul style="list-style-type: none"> • The torque tool shall be able to interface with a .014" guidewire to provide 0.2 in-oz of torque to the guidewire.
<p>J-Straightener Requirement</p>	<ul style="list-style-type: none"> • The J-straightener shall act as a funnel making it easier to insert the guidewire into a lead or another compatible device.

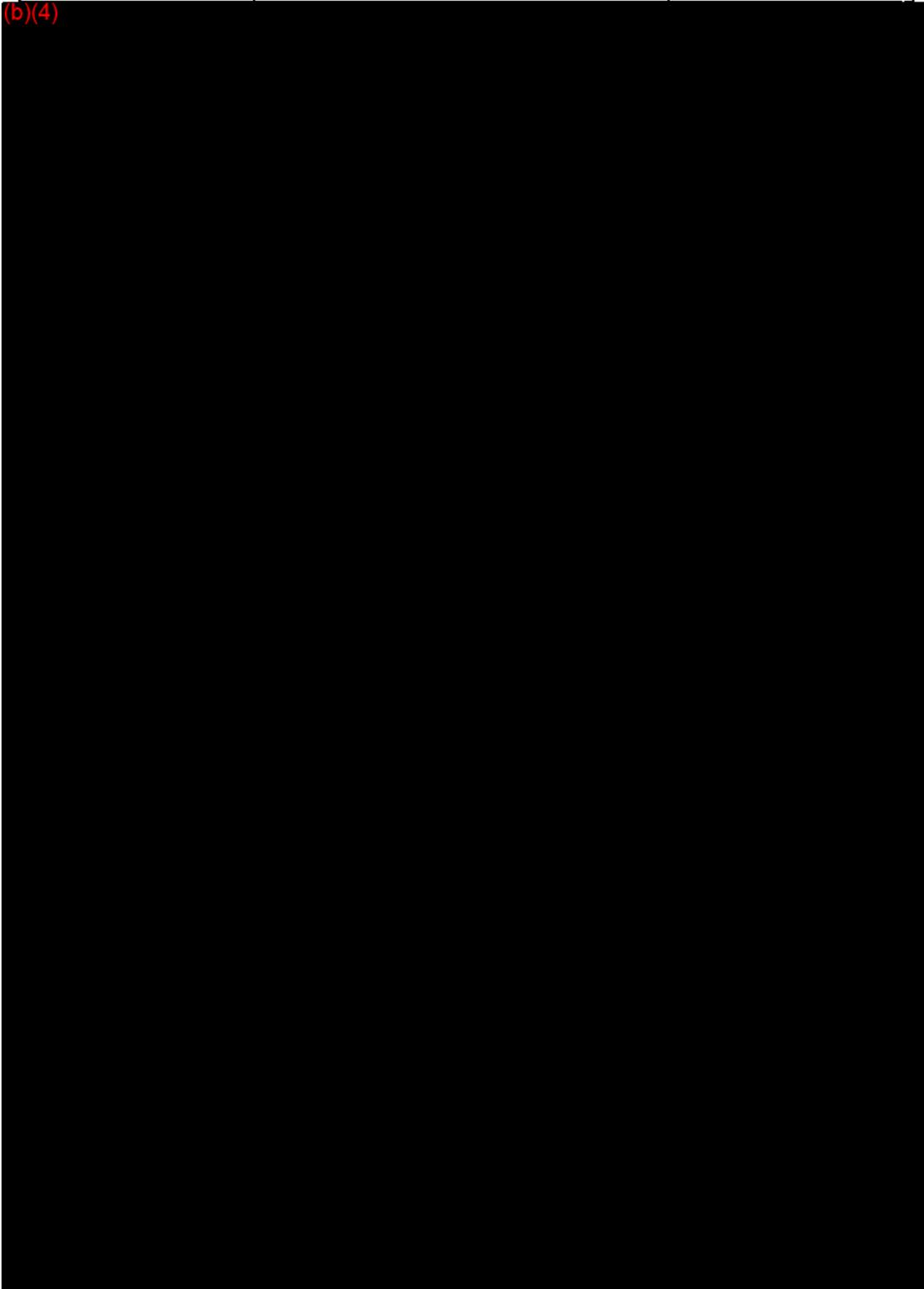
MediGuide Guidewire Torque Clip Requirements

- The guidewire clip shall be compatible with the MediGuide Enabled Guidewire. The clip shall allow the passage of guidewire without any damage.
- The guidewire clip shall be compatible with the 1258 QuickFlex Micro lead and the 1458 Quartet lead (the lead connector shall fit within the distal overmold portion of the clip).
- When unclipped, the MediGuide Enabled Guidewire is able to be advanced by a minimum of 6.0 cm distally into the lead without the need to detach the clip from the guidewire.
- The over mold portion of the clip must not delaminate after applying a minimum of 0.2 lbs axial force 5 times.
- The guidewire clip must attach to the 1258 QuickFlex Micro and the 1458 Quartet Lead proximal connector with a minimum of 0.2 lbs axial force 5 times and shall not damage the proximal lead connectors.
- The clip (guidewire attachment portion) must be capable of applying 0.2 in-oz torque to the guidewire when it is fixed in place.
- The actuation portion of the clip must withstand 5 actuation cycles without damage.
- A thumb pad will have a lead connector outline printed upon it in black ink indicating lead connector to clip orientation.
- The hinges shall be free of splitting.
- The torquer nut shall be restrained by the torquer body.
- The hinge portion of the clip must withstand

Summary of Tests and Results

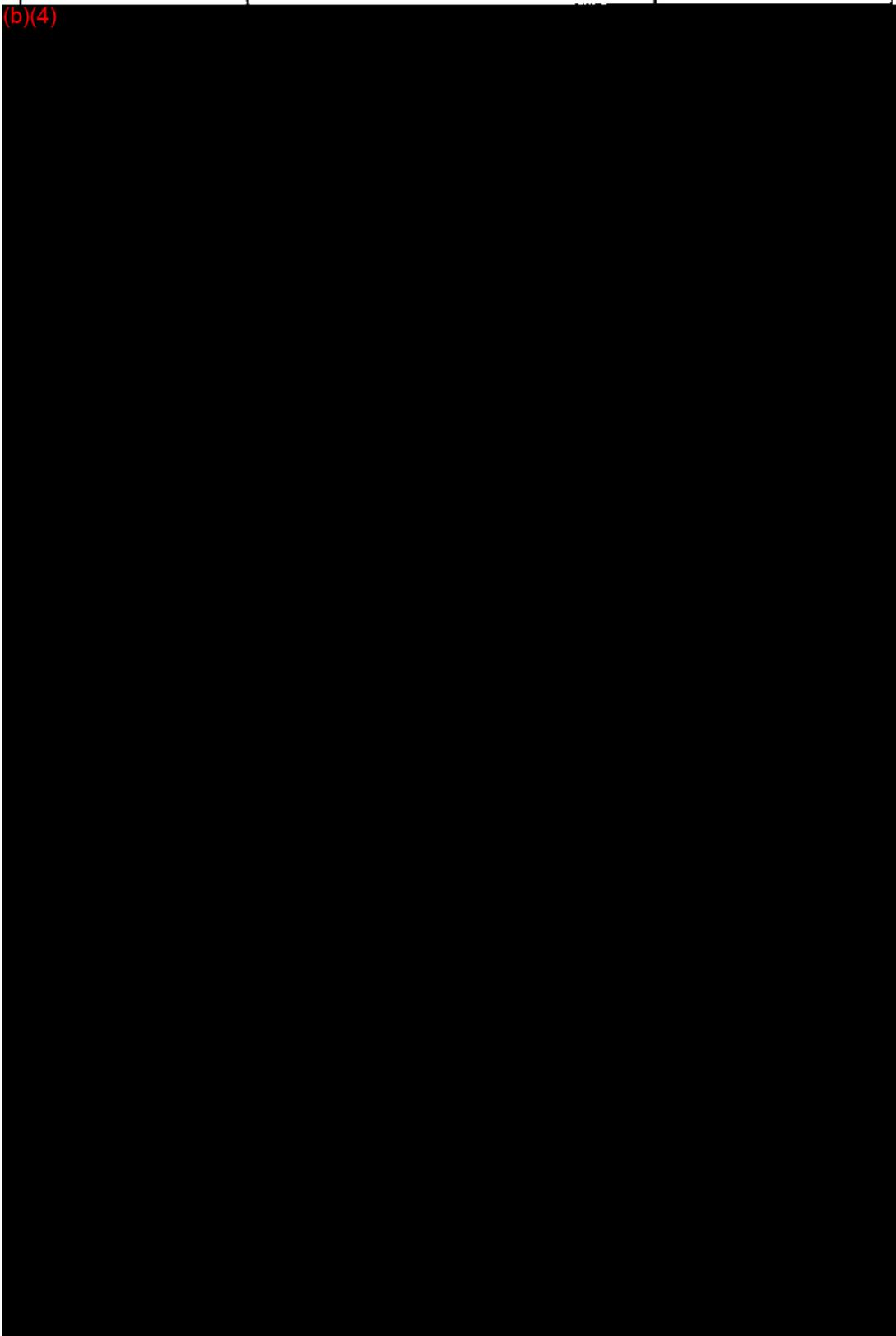
Table: Summary of Bench Tests and Results

Test	Acceptance Criteria	Result
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Test	Acceptance Criteria	Result
------	---------------------	--------

(b)(4)



(b)(4) b	Acceptance Criteria	Result
		(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

Test	Acceptance Criteria	Result
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(b)(4)

(b)(4)

Additional information should be asked about the (b)(4)
 (b)(4) (b)(4)

XII. Performance Testing – Animal

None

XIII. Performance Testing – Clinical

None

XIV. Substantial Equivalence Discussion

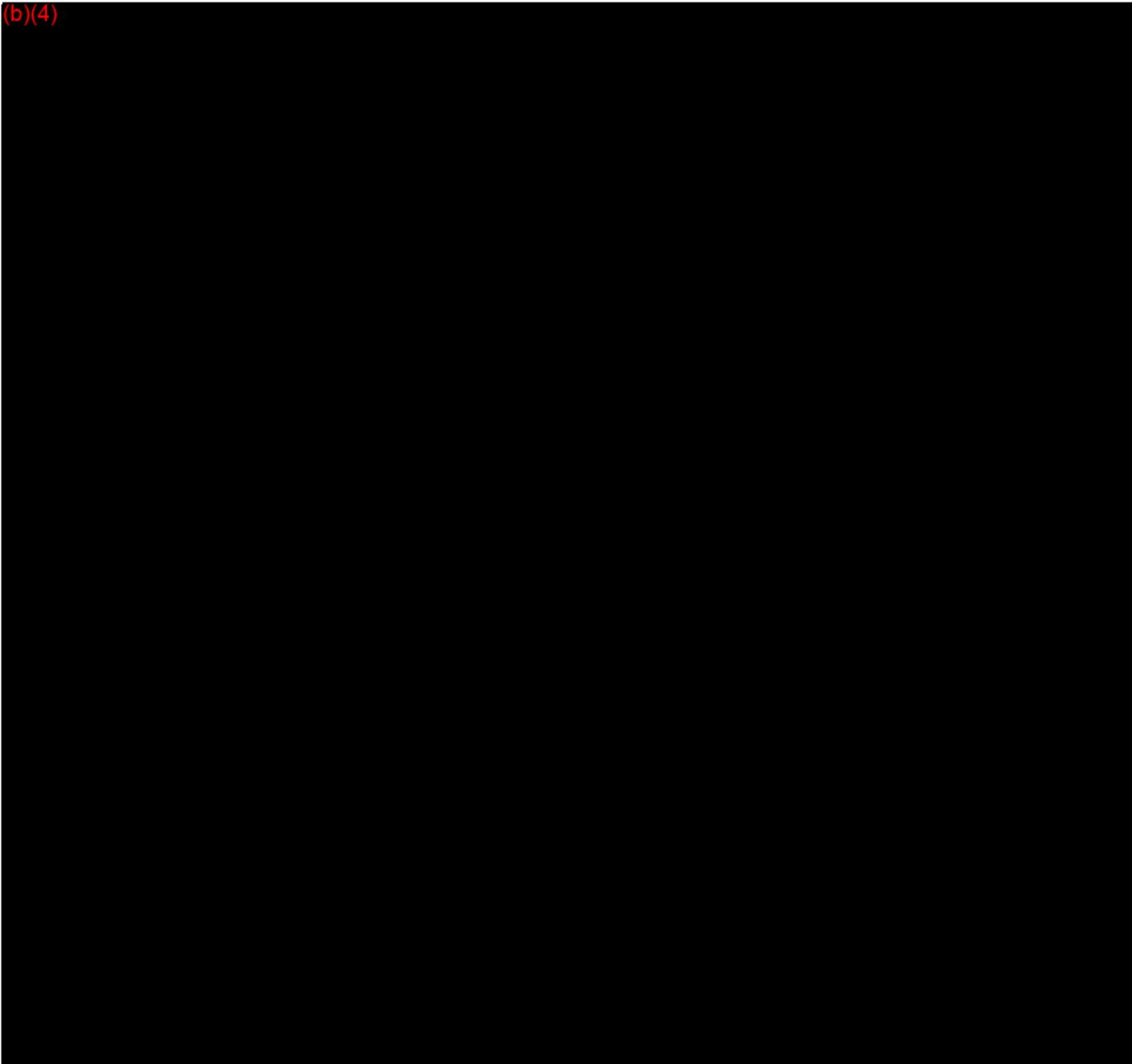
	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness: tip coating adherence + trackability + electrical integrity testing

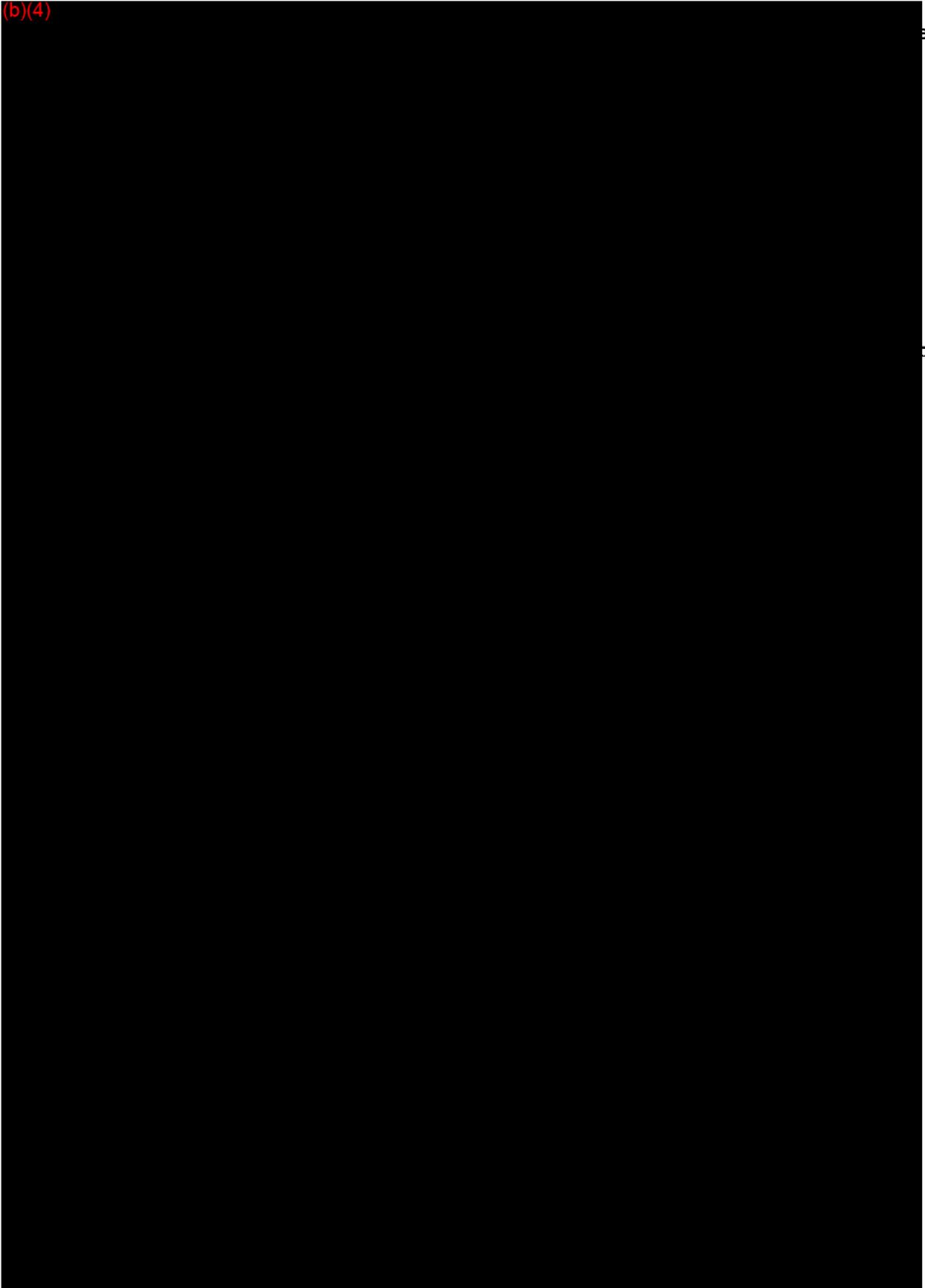
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: electrical integrity testing
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Previous Deficiencies and Summary Responses

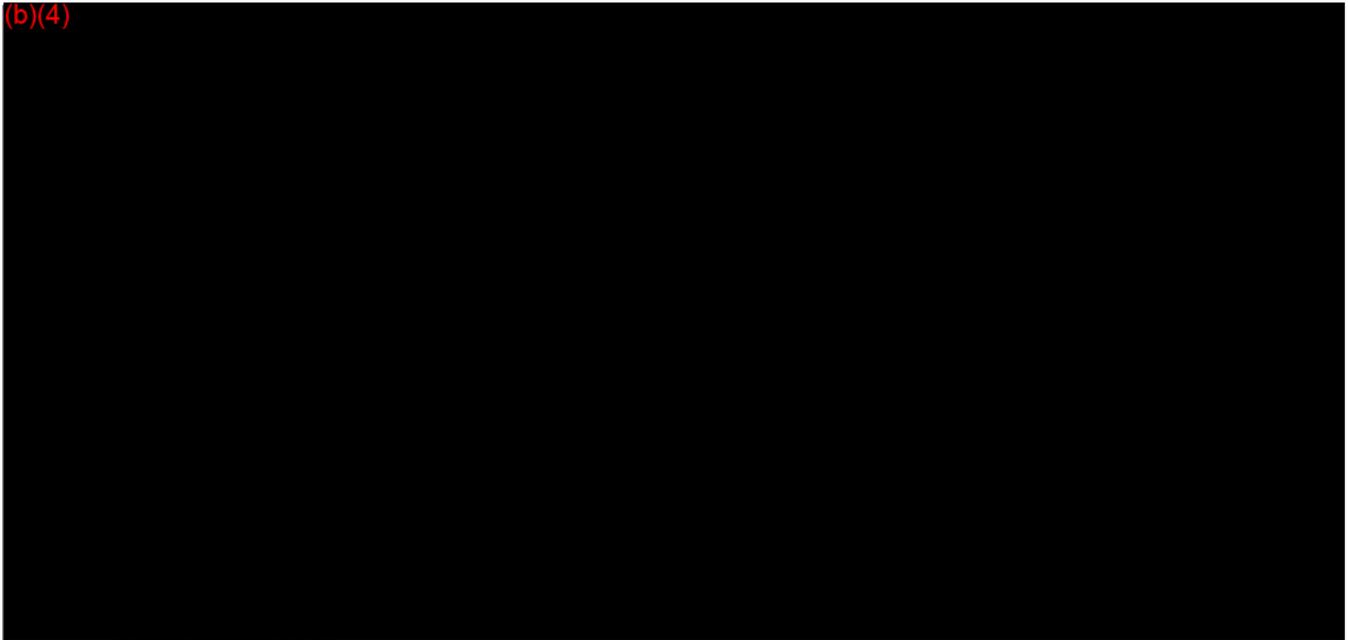
(b)(4)



(b)(4)



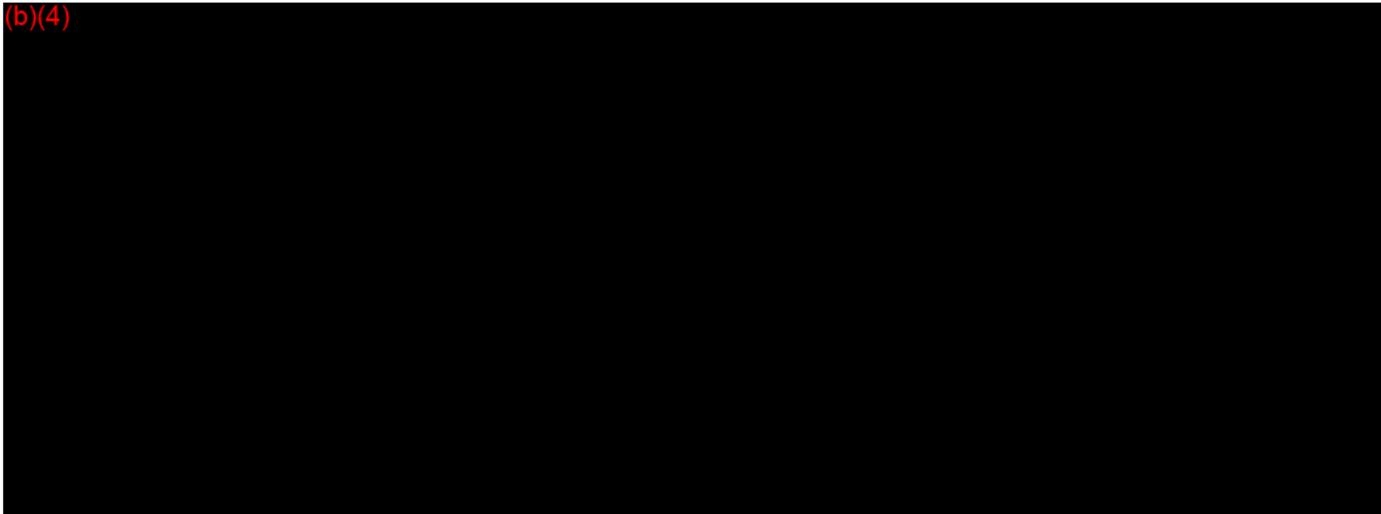
(b)(4)



report (00036227).

XVI. Contact History

(b)(4)



XVII. Recommendation

The recommendation is **Substantial Equivalence (SE)**. Since adequate response has been received and reviewed, the device should be classified under:

Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter, Guidewire
Regulatory Class: II (two)
Product Code: 74 DQX

SEE EMAIL IN LIEU OF REVIEWER'S SIGNATURE

concur: [Signature] 5/8/12

Aguel, Felipe

From: Lacy, Frank
Sent: Monday, May 07, 2012 6:22 PM
To: Aguel, Felipe
Subject: FW: K120298 CPS Excel MediGuide Enabled guidewire interactive questions

Attachment to e-mail containing review memorandum for K120298.

From: Lacy, Frank
Sent: Monday, May 07, 2012 6:08 PM
To: Canan, Colleen
Subject: RE: K120298 CPS Excel MediGuide Enabled guidewire interactive questions

Hi Ms. Canan,

(b)(4)



Thanks for the prompt attention to this matter.

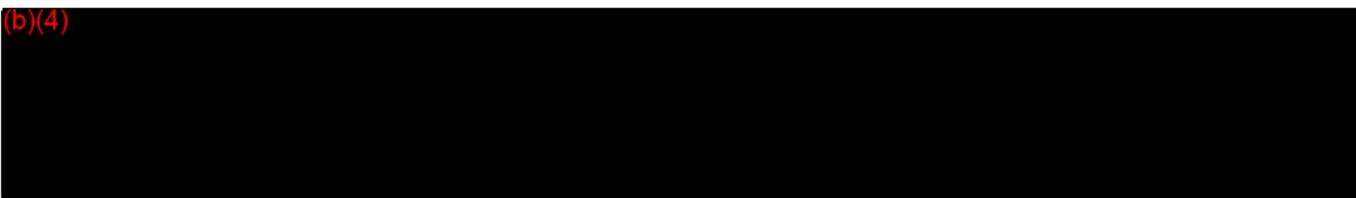
Regards,
Frank

From: Canan, Colleen [mailto:CCanan@sjm.com]
Sent: Monday, May 07, 2012 5:46 PM
To: Lacy, Frank
Subject: K120298 CPS Excel MediGuide Enabled guidewire interactive questions

Dear Mr. Lacy-

In regards to your questions via phone today, the following information is being provided for the CPS Excel MediGuide Enabled guidewire:

(b)(4)



If you have any further questions, please do not hesitate to contact me.

Sincerely,

Colleen

Colleen Canan, RAC
Staff Regulatory Affairs Specialist
St. Jude Medical

818-493-2960

This communication, including any attachments, may contain information that is proprietary, privileged, confidential or legally exempt from disclosure. If you are not a named addressee, you are hereby notified that you are not authorized to read, print, retain a copy of or disseminate any portion of this communication without the consent of the sender and that doing so may be unlawful. If you have received this communication in error, please immediately notify the sender via return e-mail and delete it from your system.

Standard Operating Procedures for 510(k) Summaries

- 1) If a 510(k) submitter decides to submit a 510(k) summary, as per 21 CFR 807.87(h), they need to follow the content requirements as per 21 CFR 807.92.
- 2) If during the review of the 510(k), the submitter decides to switch to a 510(k) statement, as per 21 CFR 807.87(h), they may do so while the 510(k) is under review. They must follow 21 CFR 807.93 for a 510(k) statement.
- 3) The 510(k) summary is written by the 510(k) submitter, but FDA will agree with the content prior to clearing any 510(k).
- 4) The 510(k) summary needs to agree with the final classification decision of FDA, e.g., the predicate classification needs to match the FDA classification decision. The submitter may need to revise the summary while the 510(k) is under review. In other words, the 510(k) summary will need to reflect the predicate(s) and decision made by FDA. The submitter will then need to revise the summary while the 510(k) is under review.
- 5) The IFU provided in the 510(k) summary needs to match the IFU statement that is determined to be substantially equivalent
- 6) The 510(k) summary should reflect all the testing done by the 510(k) submitter to demonstrate substantial equivalence. This may include testing that FDA did/would not require to demonstrate substantial equivalence, but would include all testing that FDA does/would require to demonstrate substantial equivalence.
- 7) If the 510(k) summary is deficient, the deficiency(ies) may be put in an AI letter or handled through interactive review.
- 8) The 510(k) may not be found to be substantially equivalent until the 510(k) summary meets the regulatory requirements of 21 CFR 807.92.
- 9) If, after interactions, a 510(k) submitter does not revise the 510(k) summary as requested and we disagree with their rationale, the 510(k) may be found not substantially equivalent for lack of required data/information.
- 10) Neither the 510(k) summary, nor 510(k) statement, are needed if the decision is other than SE.
- 11) The 510(k) summary will go on FDA's website approximately the 5th of the month following any SE decision.

510(k) SUMMARY REQUIREMENTS CHECKLIST 21 CFR 807.92

All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the	✓		

	date the summary was prepared			
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	✓		
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	✓		
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.	✓		
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence	✓		
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)	✓		
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.	✓		



COVER SHEET MEMORANDUM

From: Reviewer Name Frank Lacy
Subject: 510(k) Number K120298
To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____ see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?		X	
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
Is clinical data necessary to support the review of this 510(k)?		X	
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		X	
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <=21			X

adutt

Neonate/Newborn (Birth to 28 days)	
Infant (29 days -< 2 years old)	
Child (2 years -< 12 years old)	
Adolescent (12 years -< 18 years old)	
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	
Nanotechnology	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.



Regulation Number _____ Class* **TH** Product Code _____
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

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

Final Review: _____ (Division Director) (Date)

K120298

Date: March 22, 2012
 To: The Record
 From: Frank Lacy

Office: ODE
 Division: DCD

510(k) Holder: St. Jude Medical
 Device Name: CPS Excel™ MediGuide Enabled™ Guidewire and accessories
 Contact: Colleen Canan
 Phone: (818) 493-2960
 Fax: (818) 493-3615
 Email: ccanan@sjm.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce a new CPS Excel™ MediGuide Enabled™ Guidewire and accessories into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?			

The CPS Excel guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The design of the CPS Excel, MediGuide Enabled guidewire is based on the design of the commercially available CPS Courier guidewire (predicate) with the accommodation of a MediGuide sensor. The guidewire contains a magnetic sensor allowing it to be tracked using the MediGuide System.

Like its predicate device, the CPS Excel MediGuide Enabled guidewire is intended for use in the coronary and peripheral vasculature. The diameter of the guidewire is sized to allow it to pass through the lumen of a LV pacing lead. The MediGuide enabled guidewire has three distinct regions: proximal connector region, middle region (guidewire body), and the distal tip region.

Proximal Connector Region
Electronic interface/connection of the MediGuide guidewire is accomplished at the proximal end of the guidewire. The proximal end contains two (b)(4) rings which are separated and electrically isolated from one another by polymeric rings. The (b)(4) have a diameter similar to that of the guidewire body thus allowing passage through the lumen of a pacing lead. The (b)(4) rings and polymeric rings are supported by a core wire which is bonded to the guidewire body. The sensor cabling runs alongside the core wire and are connected to the (b)(4) rings.

Middle Region

The guidewire body consists of a hollow (b)(4) tube that provides a lumen for passage of the sensor conductor wires (cables). The stainless steel tube also contains a (b)(4) core wire (safety wire) which is securely attached to both the distal and proximal ends of the guidewire. The guidewire is coated with (b)(4), to ensure sufficient lubricity to the (b)(4) wire. The predicate CPS Courier guidewire is also coated with PTFE.

Distal tip region

The distal most component of the Excel guidewire contains the MediGuide Sensor. The sensor is securely attached to the guidewire via the core wire. The MediGuide sensor consists of copper wire coiled around a metal core and connected to a sensor cable. Immediately proximal of the MediGuide sensor is a (b)(4) coil (Pt) which provides radiopacity for tracking on live fluoroscopy. The distal portion of the (b)(4) tube is cut in a helical pattern to provide a flexible tip. The pitch of the cut varies to provide varying degrees of stiffness. The stiffness of the helical cut section increases from proximal to distal, like its predicate wire (CPS Courier). The distal portion of the stainless steel tube is also ground down to a smaller diameter than the guidewire body. The smaller diameter provides less stiffness and also allows space for a soft polymer (b)(4) coating. The soft polymer coating is identical to the predicate wire and encapsulates the entire distal region of the guidewire including the MediGuide Sensor. The (b)(4) coating is then coated with a hydrophilic coating to provide lubricity.

Description of Accessories:

Each guidewire kit contains one guidewire and pouched J-straightener and torque tool. The guidewire is packaged in a spiral dispenser with a luer adapter on the outer end. The dispenser which is retained in its shape with (b)(4) clips and has one anti-migration device which grips one point of the wire to prevent its movement within the hoop during transportation. The polymer coated distal tip of the guidewire lies along the outside diameter of the dispenser nearest the luer adapter. Each dispenser assembly and pouched J-straightener and torque tool are placed in an outer pouch and sealed.

The Mediguide™ extension cable accessory is a flexible, insulated cable that is used to connect the CPS Excel Mediguide Enabled guidewire via the MediGuide guidewire connector to the Mediguide™ System.

The purpose of the cable is to provide the implanting physician with a sterile connection for the desired delivery tool. The MediGuide Enabled delivery tool needs to be connected to the MediGuide Cath Connect interface box to be able to track the tool on the MediGuide system. The MediGuide extension cable is used to bridge the gap between the MediGuide Cath Connect interface box and the MediGuide Enabled delivery tool. Thus the MediGuide extension cables creates an extra layer of protection by allowing the physician to keep the MediGuide Enabled delivery tool completely in the sterile field and offering the possibility to connect, disconnect and change delivery tools without having to extend beyond the sterile field. The length of the extension cables is sufficient enough to lay them over the sterile drapes without pulling either ends.

The MediGuide extension cable consists of three connectors on each side. The three connectors allow connections of up to three MediGuide Enabled delivery tools to the MediGuide system. The cables that connect to the MediGuide system consists of standard ODU connectors that are plugged into the MediGuide system's Cath Connect box. The other end of the cables is comprised of standard Redel connectors that are magnetically shielded and are compatible with the MediGuide Enabled delivery tools. Trifurcated cables on both ends are color coded respectively to identify correct device connection on both ends.

MEDIGUIDE GUIDEWIRE CONNECTOR

The MediGuide guidewire connector accessory is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire to the MediGuide extension cable. The guidewire is inserted into the connector until it bottoms out. Once the guidewire cannot be pushed any further, the nut on the connector end is tightened to fixate the guidewire in the connector. Inside the molded connector housing is a printed circuit board (PCB) which is wrapped with magnetic shielding. The PCB has contact slots that connect with the electrical contacts of the guidewire for electrical functionality. The other end of the MediGuide guidewire connector is a standard Redel connector that is magnetically shielded and connects to the MediGuide Extension Cable.

MEDIGUIDE GUIDEWIRE TORQUE CLIP

The MediGuide guidewire torque clip is an accessory that is used to torque the guidewire. It is also used to secure the LV pacing lead and guidewire together. Locking the tip of the CPS Excel MediGuide Enabled guidewire with the tip of a LV pacing lead enables real-time tip visualization and navigation of the LV pacing lead that does not contain a MediGuide sensor.

The guidewire clip has two [REDACTED] (b)(4) molded arms attached by a hinge that allows the clip to pivot over the guidewire path. These arms are defined as the clip body and the torque body. The end of the clip body that is opposite of the hinge pin includes two opposing clip arms which can be pushed so as to insert or release the lead connector. A graphic of a lead connector is pad printed on one of the clip arms to guide the user in locating the lead connector within the clip arms. The end of the torque body opposite of the hinge pin contains a tightening screen that is used to secure the guidewire to the torque clip.

The MediGuide Enabled guidewire is passed through the torque clip and the pacing lead. The tip of the guidewire is then matched with the tip of the pacing lead and the nut on the clip is tightened to lock the two together. When inserted inside the anatomy, the implanting physician can now visualize the tip of the pacing lead by using the guidewire sensor locked at its tip. To advance the guidewire past the lead tip, the implanting physician would compress the finger tabs to remove the clip from the lead and advance the clip towards the lead connector. Similar to a typical over-the-wire technique, the physician can now safely track the lead over the wire by holding the guidewire in position and advancing the lead over the wire until it reaches the distal end of the wire. To re-position the guidewire with the tip of the lead, reconnect the clip to the lead connector. Thus the MediGuide guidewire torque clip gives the physician the ability to visualize the lead tip while tracking the lead safely over the wire at the same time.

The manufacturer has indicated that the device is the St. Jude Medical CPS Excel™, MediGuide Enabled™ guidewire is a MediGuide enabled guidewire with a hydrophilic coating. The CPS Excel, MediGuide Enabled guidewire contains a magnetic sensor allowing it to be visualized using the MediGuide system.

Concise Description of the Device-CPS Excel MediGuide Enabled Guidewire

The CPS Excel, MediGuide guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The guidewire comes in three unique base models distinguished by their unique distal flexibility profiles. Each base model comes with an angled distal tip. The guidewire contains a magnetic sensor allowing it to be tracked using the MediGuide System.

Concise Description of the Accessory- MediGuide Extension Cable

The St Jude Medical MediGuide extension cable is a flexible, insulated cable constructed of metal and plastic materials. This cable is compatible for single use only.

Concise Description of the Accessory- MediGuide Guidewire Connector

The MediGuide guidewire connector is a flexible, insulated cable that is used to connect the CPS Excel MediGuide Enabled guidewire to the MediGuide extension cable.

Concise Description of the Accessory- MediGuide Guidewire Torque Clip

The MediGuide torque clip is an accessory that is used to torque the guidewire. It is also used to secure the LV pacing lead and guidewire together. Locking the tip of the CPS Excel MediGuide Enabled guidewire with the tip of a LV pacing lead enables real-time tip visualization and navigation of the LV pacing lead that does not contain a MediGuide sensor.

Models records processed under FOIA Request # 2015-3393; Released by CDRH on 09-23-2015
 The CPS Excel MediGuide Enabled guidewire consists of guidewires available in different stiffness profiles. The CPS Excel MediGuide Enabled guidewires come in three unique base models distinguished by their unique distal flexibility profiles. Each base model comes with an angled distal tip. The guidewires all come in 195 cm lengths.

Model Number Description

- DS2M027: MediGuide guidewire- Soft (S)
- DS2M028: MediGuide guidewire- Medium (M)
- DS2M029: MediGuide guidewire- Extra Firm (XF)

IV. Indications for Use

According to the manufacturer, "The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.

V. Predicate Device Comparison

see Comparison Table below

Table : Comparison Table

	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) K073082	MediGuide Measurement Catheter (GMC) (Predicate Device) K091780
Product Code	DQY	DQX	DQO
Regulation	870.1330	870.1330	870.1200

<p>Use</p> <p>Records processed under FOIA on 09-23-2015</p>	<p>Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy.</p>	<p>are intended for use in coronary and peripheral vasculature.</p>	<p>gMPS enabled intravascular catheter intended for the diagnostic evaluation of the coronary vasculature in patients who are candidates for coronary angiography and/or Percutaneous Coronary Intervention (PCI)</p> <p>The GMC is used with compatible</p>
	<p>St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)</p>	<p>St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) K073082</p>	<p>MediGuide Measurement Catheter (GMC) (Predicate Device) K091780</p>
			<p>gMPS system to enable real-time tip positioning and navigation, quantitative reconstruction, qualitative 3D foreshortening indications, and landmarking</p> <p>The System is indicated for use as an adjunct to fluoroscopy.</p>

Description Records processed under FOIA Request # 2015-3393, Released by CDRH on 03-20-15	Enabled guidewire is a 0.014" MediGuide Enabled guidewire with a hydrophilic coating that is used to facilitate access in the coronary sinus during lead delivery. The key design features are: <ul style="list-style-type: none"> • (b)(4) hypo tube • (b)(4) coated SS • (b)(4) jacketed tip • Hydrophilically coated tip • Copper sensor cable • Copper sensor • Proximal (b)(4) 	Courier Guidewire is a 0.014" PTFE coated (b)(4) core wire, the distal end of which is reduced in diameter. The key design features are: <ul style="list-style-type: none"> • (b)(4) core wire • (b)(4) coated SS • (b)(4) jacketed tip • Hydrophilically coated tip 	maximal shaft Inner diameter of 1.15 mm, a tapered tip Inner diameter of 0.58 mm, and a usable length of 135 cm
	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) K073082	MediGuide Measurement Catheter (GMC) (Predicate Device) K091780
	(b)(4) conductor rings <ul style="list-style-type: none"> • (b)(4) spacers 		
OD	0.014"	Same as subject device	3.5 F
Working Length	195 cm	Same as subject device	135 cm
No. of models	3	10	1
Coating	Hydrophilic and (b)(4)	Same as subject device	PTFE
Distal End Stiffness	Soft, Medium, & Extra Firm	Extra Soft, Soft, Medium, Firm & Extra Firm	NA
Tip Shape	J-tip	Straight and J-tip	NA

Processed under FOIA Request # 2015-3393; Released by CDRH on 09-23-2015

with Navigation System			device
Measures Enabled via the Computerized System while working in conjunction with device	Real-time tip positioning and navigation	NA	Same as subject device

	St. Jude Medical CPS Excel, MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029 (Subject Device)	St. Jude Medical CPS Courier Guidewire (Predicate Devices – DSG001, DSG002, DSG003, DSG004, DSG005, DSG006, DSG007, DSG008, DSG009) . K073082	MediGuide Measurement Catheter (GMC) (Predicate Device) K091780
Sterility	Supplied Sterile	Same as subject device	Same as subject device
Tissue Contacting materials- Ground Hypo Tube	Top Coat: (b)(4)	Same as subject device	NA
Tissue Contacting Materials- Coating	(b)(4) Hydrophilic coating	Same as subject device	NA
Tissue Contacting Materials- Polymer jacket	(b)(4)	Same as subject device	NA

Table of Modifications

Design Feature	CPS Excel, MediGuide Enabled	CPS Courier	Reason for change
Guidewire body	Hypo tube	Solid core wire	Hypo tube (lumen) needed to route the sensor cable
Proximal end	(b)(4) conductor rings	No conductor rings	Conductor rings are required to connect to the sensor cable and then make a connection to the navigation system
Sensor	Encapsulated sensor at the distal end	No sensor	Sensor required to allow for tracking with a navigation system.

All technological characteristics of CPS Excel MediGuide Enabled guidewire are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the proposed device and the predicate devices, performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device.

Predicate Device(s):

**K073082; CPS Courier Guidewire; St. Jude Medical
K091780; MediGuide Guided Measurement Catheter; MediGuide**

Both the CPS Excel MediGuide Enabled guidewire and the predicate CPS Courier guidewire facilitate navigation within the coronary and peripheral vasculature.

The only technology utilized from the MediGuide Measurement Catheter (GMC) is the passive gMPS sensor set which is incorporated internally within the tip of the MediGuide Enabled guidewire to be located or read by the MediGuide gMPS System II (gMPS II) (K102905).

VI. Labeling

The sponsor provides labeling that appears to be appropriate for this Rx device. Details on how to use the MediGuide guidewire torque clip can be found in the CPS Excel MediGuide Enabled guidewire Instructions for Use (IFU) manual. This is acceptable to this reviewer.

VII. Sterilization/Shelf Life/Reuse

The proposed device is provided sterile. The CPS Excel MediGuide Enabled guidewire, accessory extension cable, and accessory guidewire connector are sterilized using (b)(4). The Sterility Assurance is 10⁻⁶. This is acceptable to this reviewer. The packaging for the CPS Excel MediGuide Enabled guidewire and accessory MediGuide extension cable, guidewire torque clip and guidewire connector are designed to protect the devices from damage and prevent contamination during storage, shipping, handling and introduction to the sterile field. The packaging designs, materials and labeling are compatible with (b) sterilization and capable of providing adequate sterile barrier for the anticipated shelf life of the device. This is acceptable to this reviewer.

SJM is currently requesting a shelf life of 1 year. The testing performed demonstrates the stability and functionality of the CPS Excel MediGuide Enabled guidewire and accessory MediGuide extension cable, guidewire connector and guidewire torque clip. The (b)(4) (b)(4) test report simulating (b)(4) (b)(4) for the CPS Excel MediGuide Enabled guidewire is provided and the accessory MediGuide extension cable is provided. The accessory guidewire connector is provided and the accessory guidewire torque clip is provided. These have been reviewed and found to be acceptable by this reviewer.

VIII. Biocompatibility

According to ANSI/AAMI/ISO 10993-1, "Biological Evaluation of Medical Devices", the fluid path contact components associated with the CPS Excel MediGuide Enabled guidewire is classified as Externally Communicating Device, Circulating Blood with Limited Contact Duration (< 24 hours). The MediGuide guidewire torque clip is a product contact device with no direct patient contact. The biocompatibility testing conducted for the guidewire torque clip addresses only the transfer of potential leachables from the guidewire torque clip to the guidewire and ultimately to the patient during use of the guidewire.

Biocompatibility Table

St. Jude Medical CPS Excel MediGuide Enabled guidewire- DS2M027, DS2M028, DS2M029	
Part name	Raw material
Ground Hypo Tube	Top Coat: (b) (b)(4)
Coating	Hydrophilic Coating (b)(4)
Polymer Jacket	(b)(4)

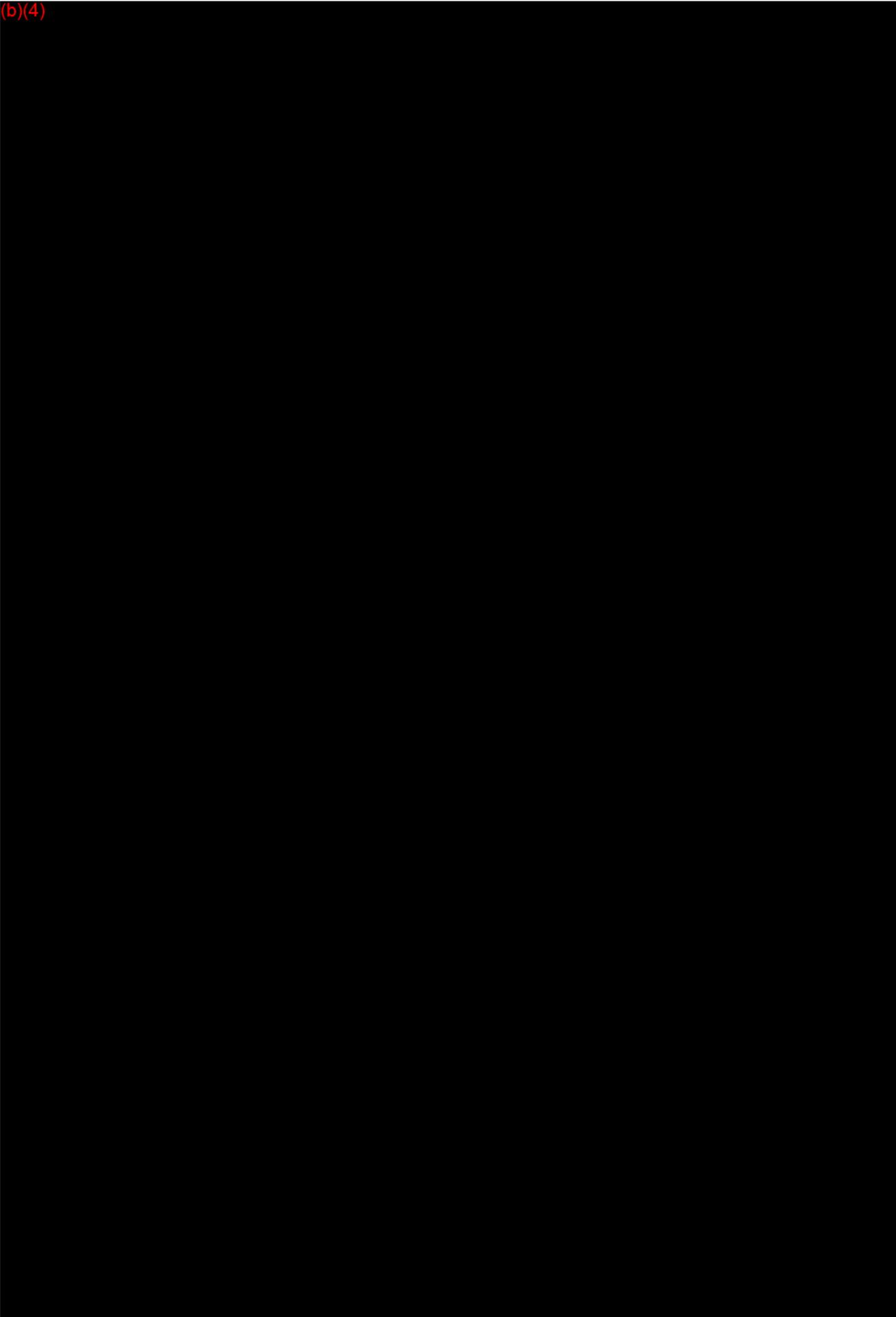
A summary of test results are provided in the Table below.

Summary of Biocompatible Testing Table

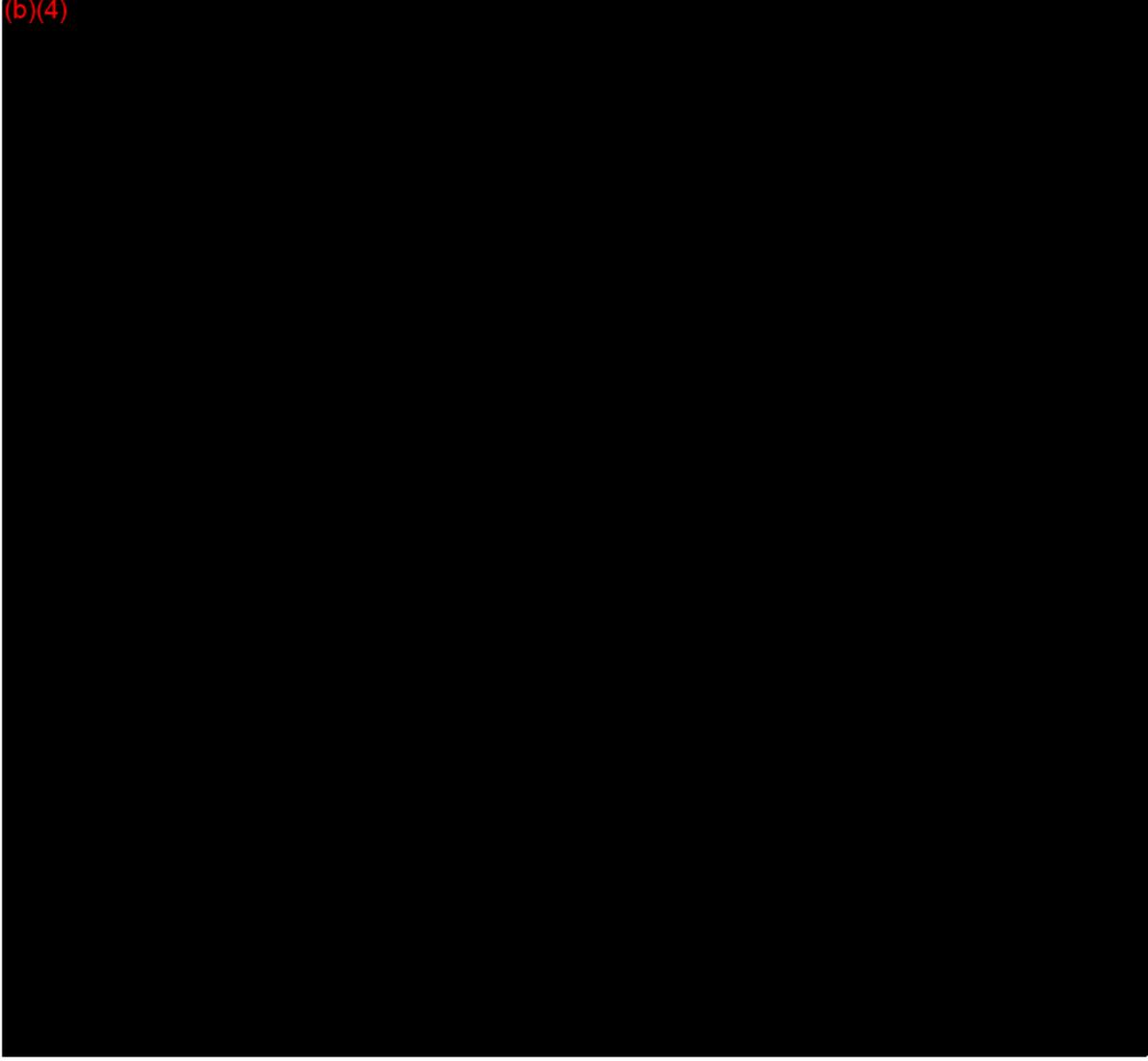
Biocompatibility Testing

Test Description	Acceptance Criteria	Result
(b)(4)	(b)(4)	(b)(4)

(b)(4)



(b)(4)



The Biocompatibility testing report of the CPS Excel MediGuide Enabled guidewire is provided. Biocompatibility testing was also conducted on the accessory guidewire torque clip and provided. The accessory MediGuide extension cable and guidewire connector are non patient contacting therefore no biocompatibility testing were required for these accessories.

The test reports are provided and complete. This is acceptable to this reviewer.

IX. Software

N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

XI. Performance Testing – Bench

Design Requirements and Performance Specifications

The Table below lists the design requirements and performance specifications for the CPS Excel MediGuide Enabled guidewire and the accessory extension cable, guidewire torque clip and guidewire connector.

Table: Design Requirements and Performance Specifications	
Parameter	Requirement/Specification
Dimensional:	<ul style="list-style-type: none"> The guidewire is to be 0.0145” in diameter or less Each guidewire shall be 195 ± 3 cm in length.
Functional Requirement:	<ul style="list-style-type: none"> Each guidewire shall have a distal coating
Guidewire	<p>Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.gov (b)(4) (b)(4)</p> <p>(b) (b) to provide radiopacity. The distal</p>

	<p>radiopaque.</p> <ul style="list-style-type: none"> The midsection of each guidewire shall have a (b)(4) coating. The Guidewire (b)(4) coating must withstand 1 insertion and withdrawal into a lead while the lead is placed in labyrinth path. The distal tip of the guidewire shall incorporate a coil for Radiopacity. The coil shall be (b)(4). The distal tip will contain a MediGuide sensor. The MediGuide sensor will be contained within the (b)(4) coating and will be attached to the guidewire via the core wire. The polymer coating will be over-coated with a hydrophilic coating. Each guidewire shall not exhibit any polymer coating damage when inserted into a device 10 times within a vessel model. Metallic components of the guidewire shall show no signs of corrosion that affects functional performance or biocompatibility test results when tested per the corrosion resistance test method described in annex B of ISO (b)(4)
<p>Structural Requirements</p>	
<p>Structural Requirements Guidewire</p>	<ul style="list-style-type: none"> The core wire acts as the safety wire for the device thus the core wire and the distal bond joint must withstand 0.5 lbs of axial load. The guidewire shall withstand a minimum of 5 turns without failure while a 0.03 lbf tensile force is applied. The guidewire must track thru a lead when it is placed into a vessel model. The guidewire must pass the (b)(4) Test described in ISO (b)(4). The guidewire must pass the (b) Test described in ISO (b)(4)
<p>Electrical Requirements</p>	
<p>Electrical Requirements Guidewire</p>	<ul style="list-style-type: none"> The proximal section of each guidewire will have electrical connections that provide compatibility with the Guidewire Connector handle/interface cable. The proximal portion

	<p>of the guide wire must withstand five (5) insertion withdrawals into the Guidewire Connector Handle without physical damage or loss of electrical integrity.</p> <ul style="list-style-type: none"> • Electrical Integrity: The electrical resistance across the two conductor rings should be between 200 and 300 ohms. The resistance from each of the conductor rings to the exposed metal on the guidewire body must be greater than 3 mega-ohm. • The electrical integrity must be maintained when the guidewire is inserted into a device 10 times within a vessel model. • The guidewire must maintain its electrical integrity when soaked in 37° C (± 2°C) saline for a minimum of 2 hours. • The polarity of the sensor shall be consistently wired to the connector. The sensor coil supply (inner) wire shall be wired to proximal connector ring and the sensor coil return (outer) wire shall be wired to
<p>Sensor Accuracy Requirements Guidewire</p>	<ul style="list-style-type: none"> • When tested under non-unidirectional AC magnetic field of 10uT, generated from 9 concurrent coils at 10-14kHz, emitted from the MediGuide system MTA (magnetic transmitter assembly) magnetic field vector with the guidewire connector placed 30 cm radially from the edge of the MTA the following is required: • Average static positional accuracy error shall be less than 0.5mm with a maximum standard deviation of 0.3mm.
<p>Torque Tool Requirement</p>	<ul style="list-style-type: none"> • The torque tool shall be able to interface with a .014" guidewire to provide 0.2 in-oz of torque to the guidewire.
<p>J-Straightener Requirement</p>	<ul style="list-style-type: none"> • The J-straightener shall act as a funnel making it easier to insert the guidewire into a lead or another compatible device.

Requirements

Records processed under FOIA Request # 2015-3396

the MediGuide Enabled Guidewire. The clip shall allow the passage of guidewire without any damage.

- The guidewire clip shall be compatible with the 1258 QuickFlex Micro lead and the 1458

Quartet lead (the lead connector shall fit within the distal overmold portion of the clip).

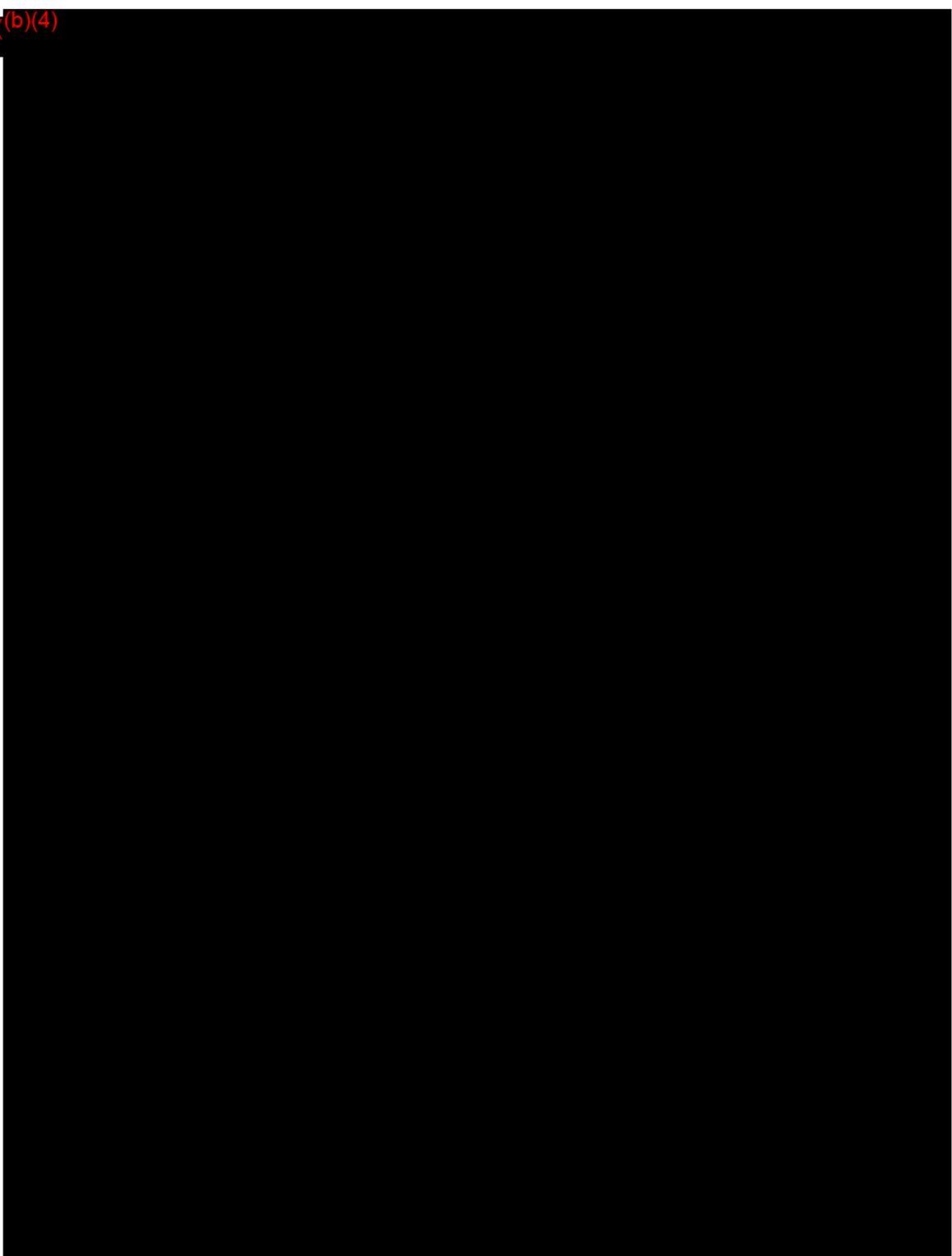
- When unclipped, the MediGuide Enabled Guidewire is able to be advanced by a minimum of 6.0 cm distally into the lead without the need to detach the clip from the guidewire.
- The over mold portion of the clip must not delaminate after applying a minimum of 0.2 lbs axial force 5 times.
- The guidewire clip must attach to the 1258 QuickFlex Micro and the 1458 Quartet Lead proximal connector with a minimum of 0.2 lbs axial force 5 times and shall not damage the proximal lead connectors.
- The clip (guidewire attachment portion) must be capable of applying 0.2 in-oz torque to the guidewire when it is fixed in place.
- The actuation portion of the clip must withstand 5 actuation cycles without damage.
- A thumb pad will have a lead connector outline printed upon it in black ink indicating lead connector to clip orientation.
- The hinges shall be free of splitting.
- The torquer nut shall be restrained by the torquer body.
- The hinge portion of the clip must withstand

Summary of Tests and Results

Table: Summary of Bench Tests and Results

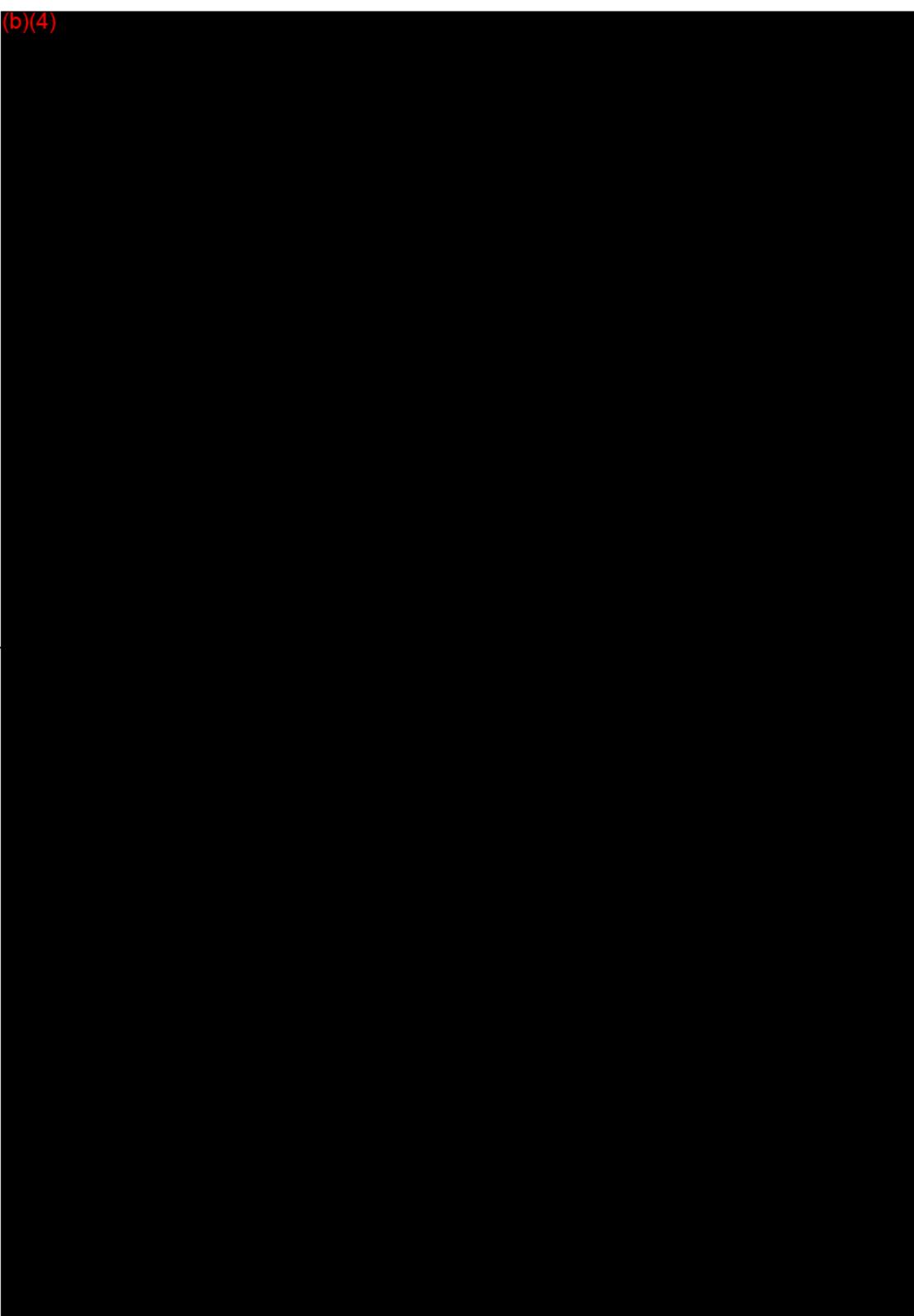
Test	Acceptance Criteria	Result
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(b)(b)(4)

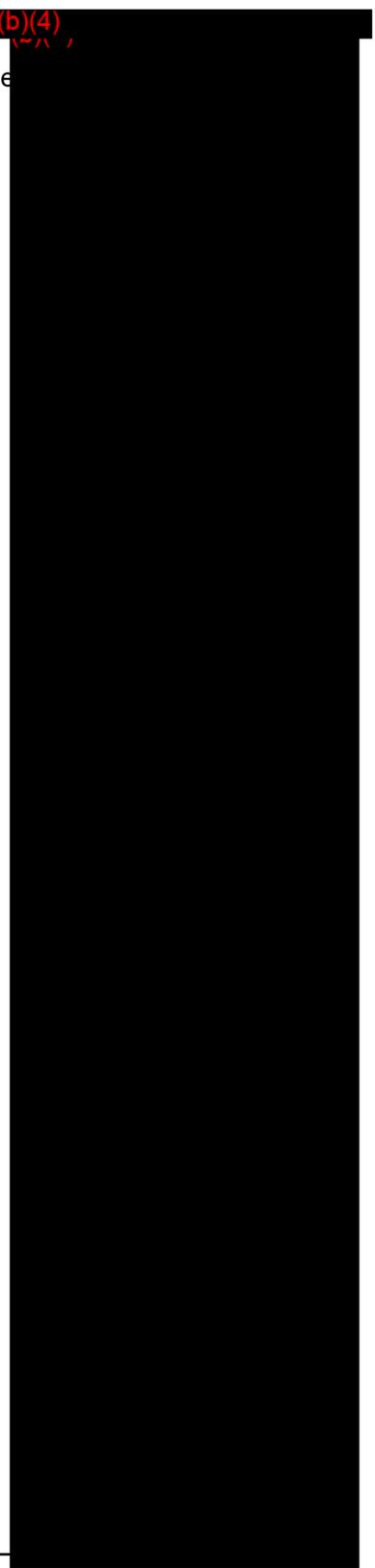


Test	Acceptance Criteria	Result
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(b)(4)



Test	Acceptance Criteria	Result
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(b)(4),
(c),



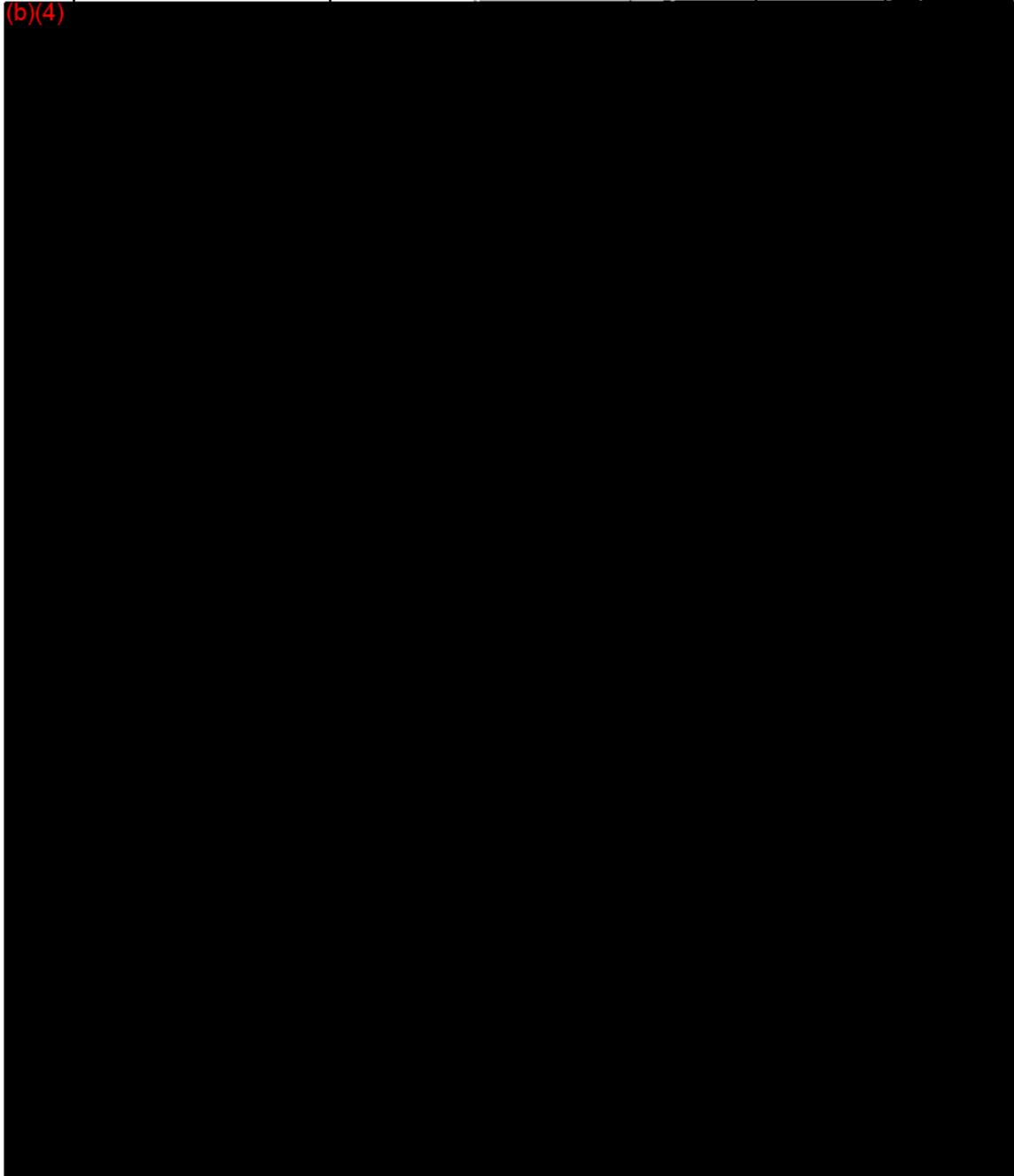
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

Test	Acceptance Criteria	Result
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(b)(4)



(b)(4)

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

XII. Performance Testing – Animal

None

XIII. Performance Testing – Clinical

None

XIV. Substantial Equivalence Discussion

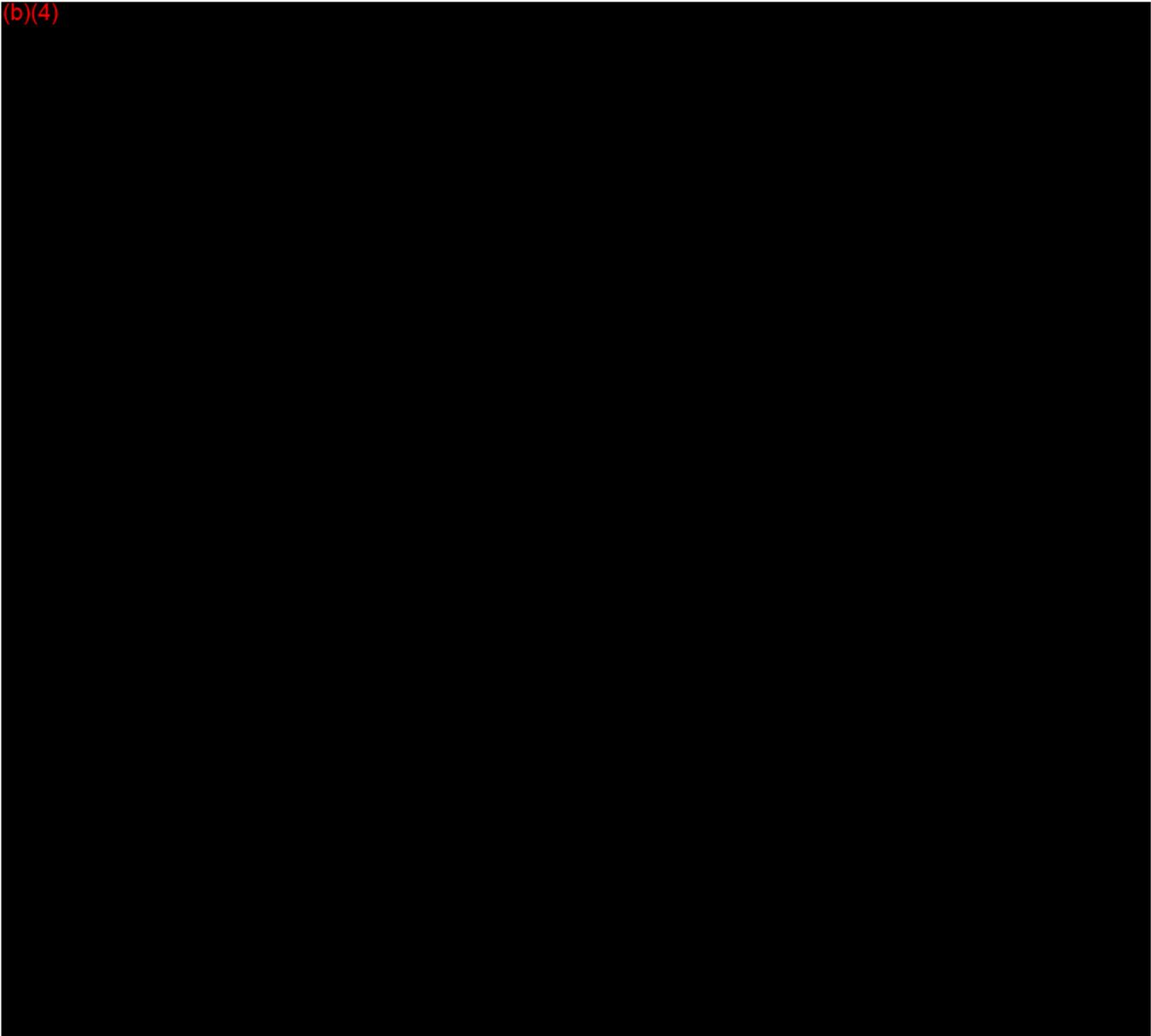
	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		X If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness: tip coating adherence + trackability + electrical integrity testing

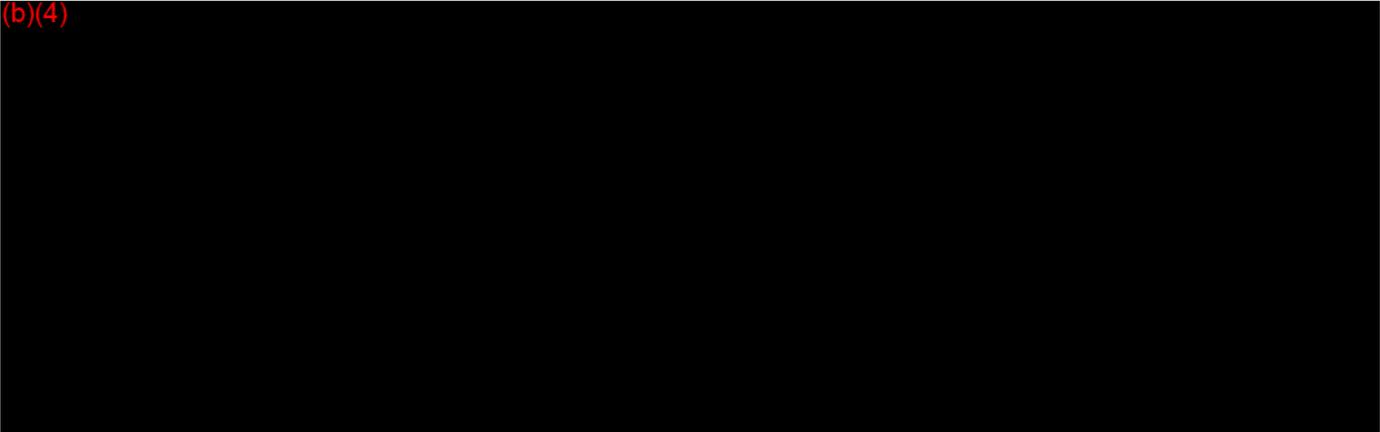
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: electrical integrity testing
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

(b)(4)



(b)(4)



XVI. Contact History

none

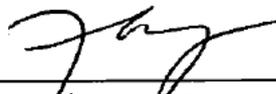
XVII. Recommendation

The recommendation is **Telephone Hold (TH)**. After an adequate response has been received and reviewed, the device should be classified under:

~~Regulation Number: 21 CFR 870.1330~~
~~Regulation Name: Catheter, Guidewire~~
~~Regulatory Class: II (two)~~
~~Product Code: 74 DQX~~

Reviewer

Branch Chief




Date

Date

3/24/12

3/26/2012

Lacy, Frank

From: Lacy, Frank
Sent: Monday, March 26, 2012 11:21 AM
To: 'ccanan@sjm.com'
Cc: Lacy, Frank
Subject: REVISED RE: K120298

Ms. Canan,

Please add the following question to the two listed below:

(b)(4)



Thanks,
Frank Lacy

From: Lacy, Frank
Sent: Thursday, March 22, 2012 6:13 AM
To: 'ccanan@sjm.com'
Subject: K120298

Hi Ms. Canan,

Please find the following for your attention. The instructions for your response are contained in the instructions below.

Regards,
Frank Lacy

March 22, 2012

Hello Ms. Canan:

I am the lead FDA reviewer for your 510(k) device application (K120298) review. I am sending this question to you via e-mail in an effort that this will facilitate your review and reduce response time. **Please answer the following questions by sending all of your correspondence through the Document Mail Center and not to me.** Please be advised that you should place the 510(k) number on all correspondence as well as be reminded that this file will be placed on HOLD until your responses are received. Receipt of your responses, by the agency, will continue the 90 day review cycle.

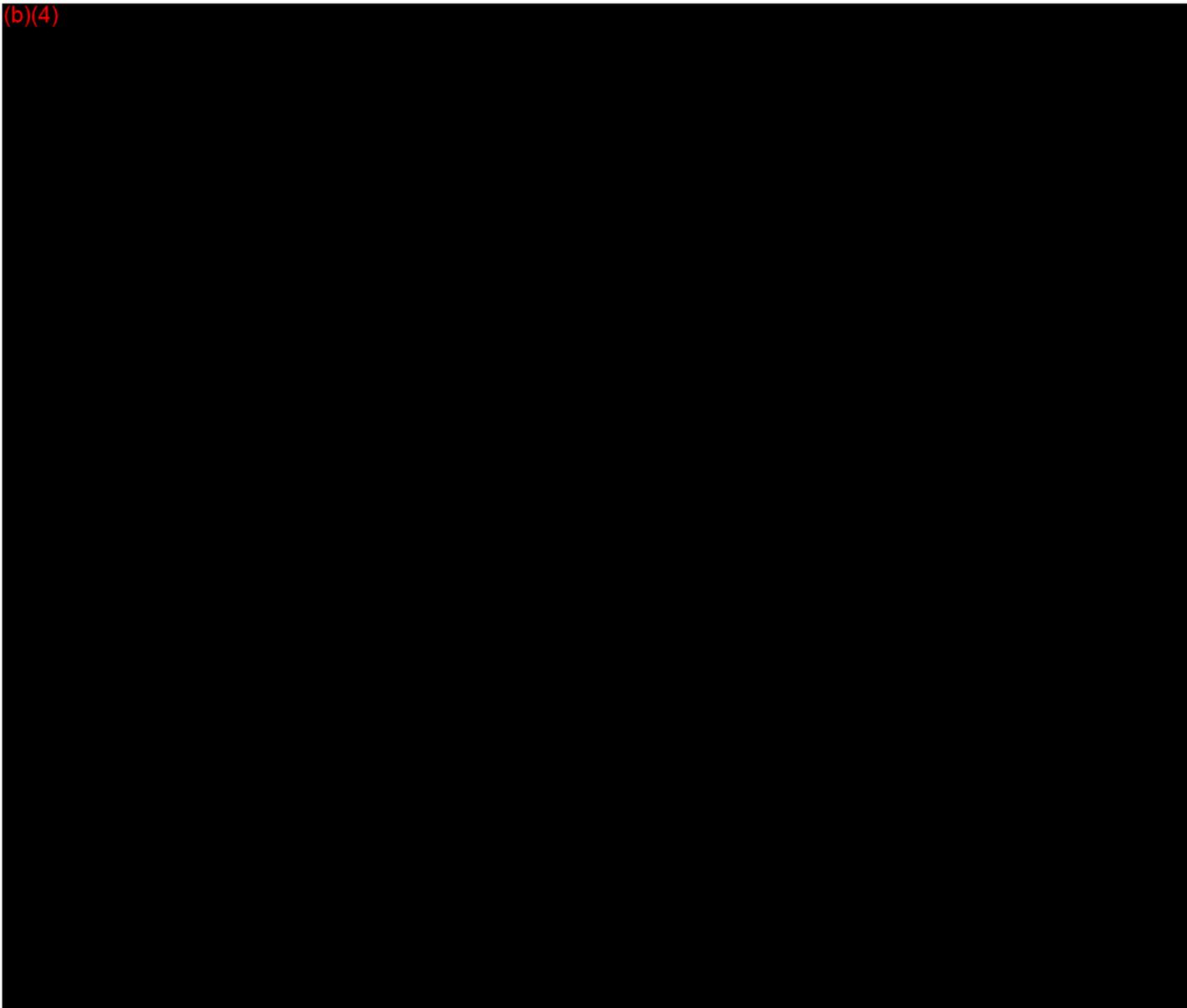
If you have any questions, please feel free to contact me via e-mail or at (301) 796-6321.

THIS E-MAIL IS INTENDED ONLY FOR THE PARTY TO WHOM IT IS ADDRESSED. IF YOU RECEIVE THIS MESSAGE IN ERROR, PLEASE RETURN TO SENDER. THANK YOU.

Question(s) for the manufacturer:

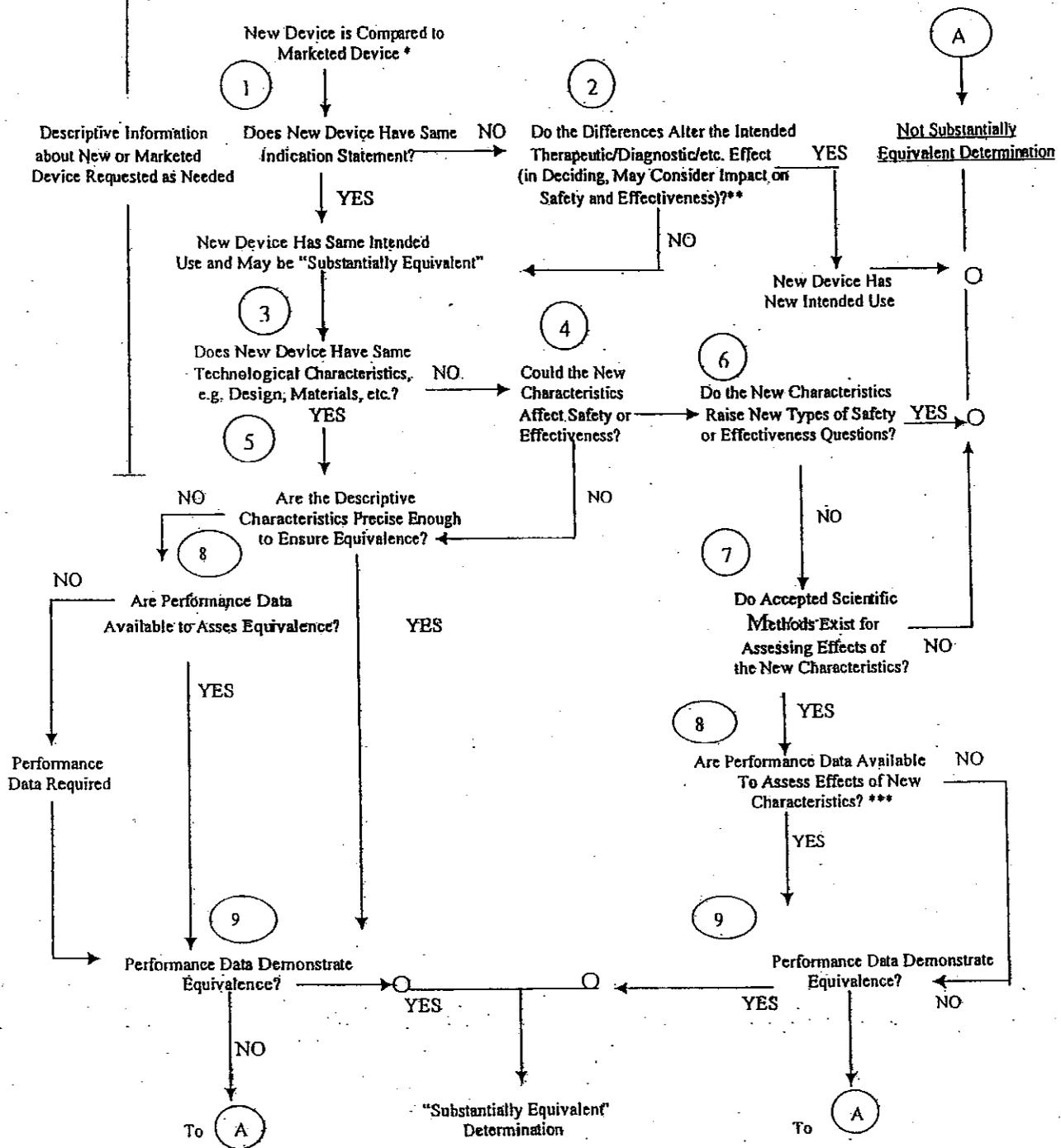
68

(b)(4)



Sincerely,
Frank Lacy; frank.lacy@fda.hhs.gov
Electrical Engineer
US Food and Drug Administration

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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sanders, Aisha *

From: Sanders, Aisha *
Sent: Tuesday, January 31, 2012 4:21 PM
To: 'ccanan@sjm.com'
Subject: K120298-ACK Letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
 U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center W066-G609

10903 New Hampshire Avenue
 Silver Spring, MD 20910-0002
 January 31, 2012

CANAN
 COLLEEN

ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISI
 15900 VALLEY VIEW CT.
 SYLMAR, CALIFORNIA 91342
 ATTN: COLLEEN CANAN

510k Number: K120298

Received: 1/31/2012

Product: CPS EXCEL MEDIGUIDE ENABLED GU

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) 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.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 e-Copy 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

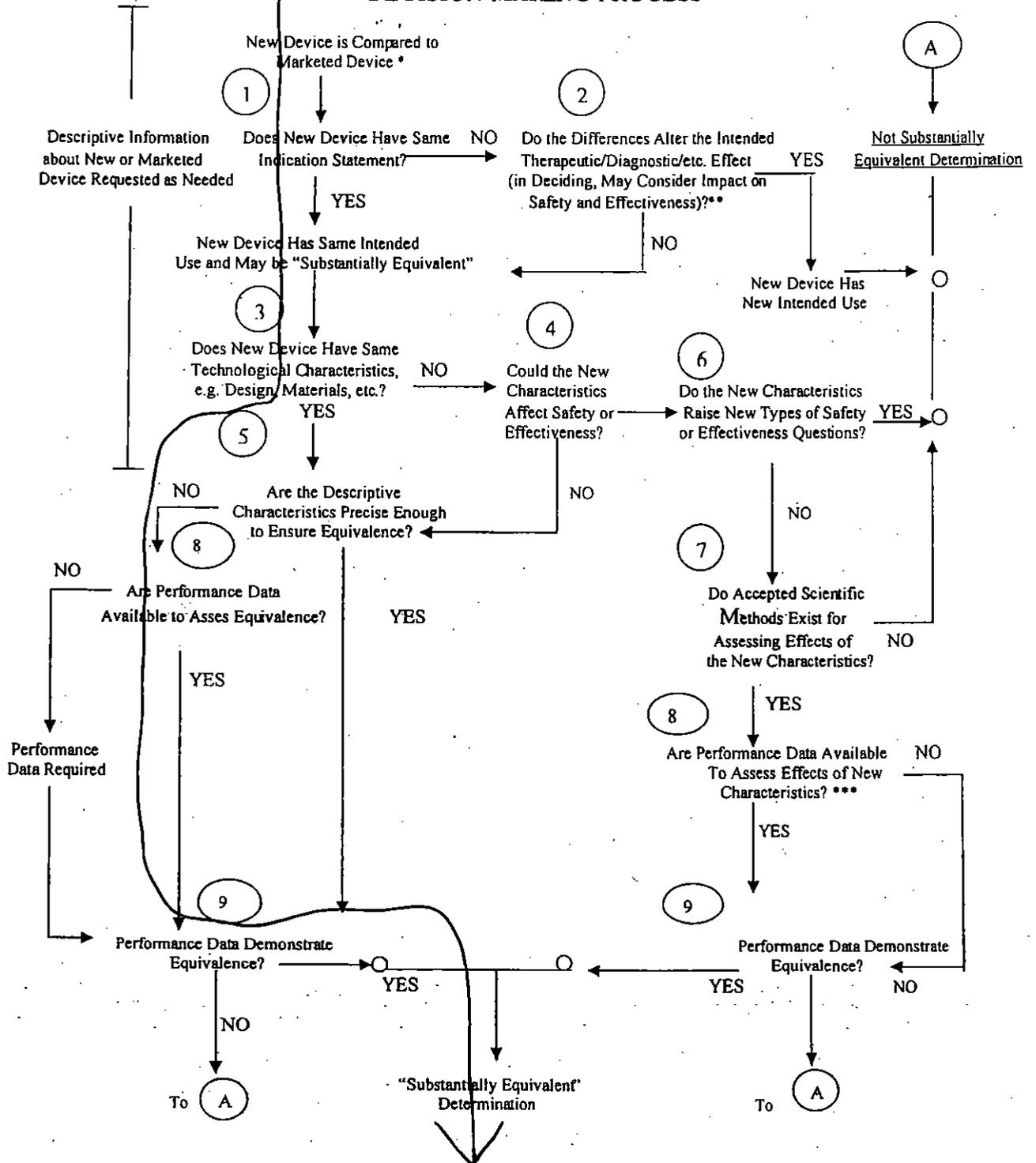
Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301) 796-5640.

Sincerely,

510(k) Staff

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



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K120298/31
CV | DCB



ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, CA 91342-3577 USA
Tel 818 362 6822
800 423 5611
www.sjm.com

April 6, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
APR 10 2012
Received K7

RE: Amendment 1 to K120298 CPS Excel MediGuide Enabled Guidewire

Dear Sir/Madam:

St. Jude Medical is submitting two paper copies of responses for K120298 to DMC and one electronic desk copy to Frank Lacy. The electronic copies are identical to the paper copies.

This amendment addresses FDA deficiencies received in emails dated March 22 and 26, 2012.

St. Jude Medical CRMD considers this application confidential and claims the protection against public disclosure in 21 CFR 812.38. Please feel free to contact me at (818) 493-2960 or via fax at (818) 493-3615 regarding this application.

Sincerely,

Colleen Canan
St. Jude Medical, CRMD
818-493-2960 (phone – direct)
818-493-3615 (fax)
ccanan@sjm.com (email)



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MORE CONTROL. LESS RISK.

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, CA 91342-3577 USA
Tel 818 362 6822
800 423 5611
www.sjm.com

April 6, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Amendment 1 to K120298 CPS Excel MediGuide Enabled Guidewire

Dear Sir/Madam:

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Sincerely,

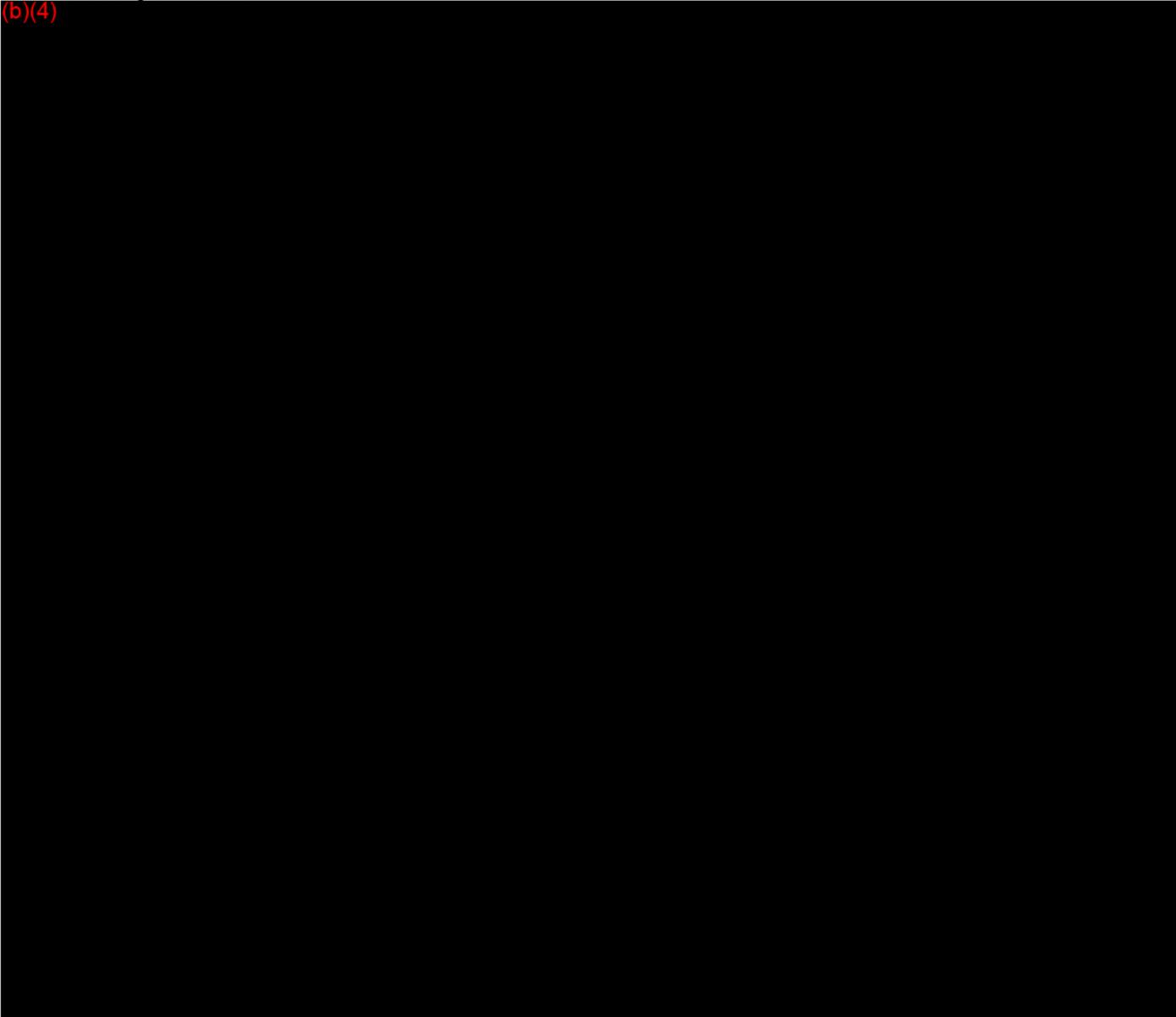
Colleen Canan
St. Jude Medical, CRMD
818-493-2960 (phone – direct)
818-493-3615 (fax)
ccanan@sjm.com (email)

Introduction:

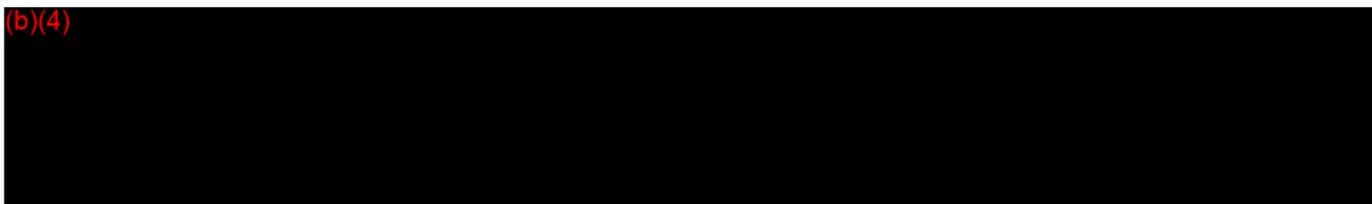
This amendment to K120298 CPS Excel MediGuide Enabled Guidewire provides responses to the FDA questions raised in emails sent on March 22, 2012 and March 26, 2012 (included in Appendix 1). In the text which follows, all FDA questions are repeated verbatim and are followed by SJM responses.

FDA Question 1

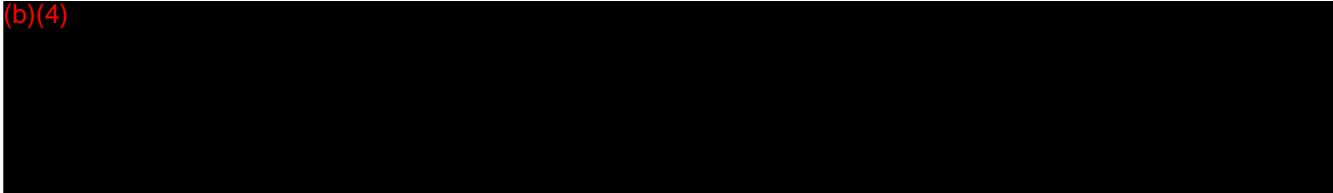
(b)(4)



(b)(4)

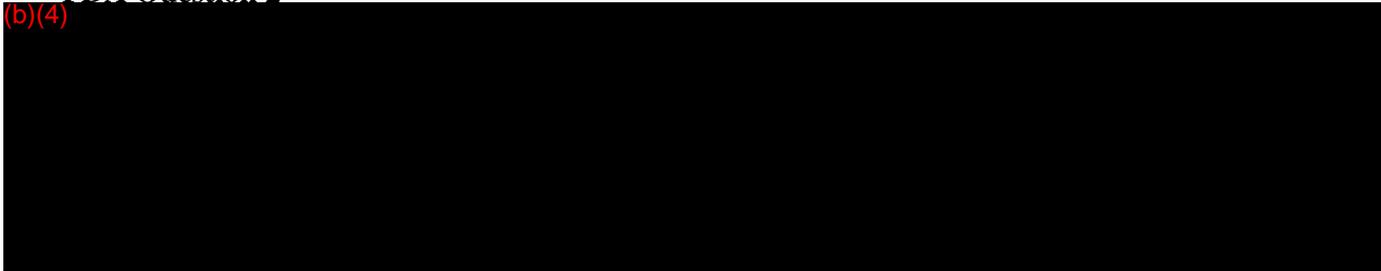


(b)(4)

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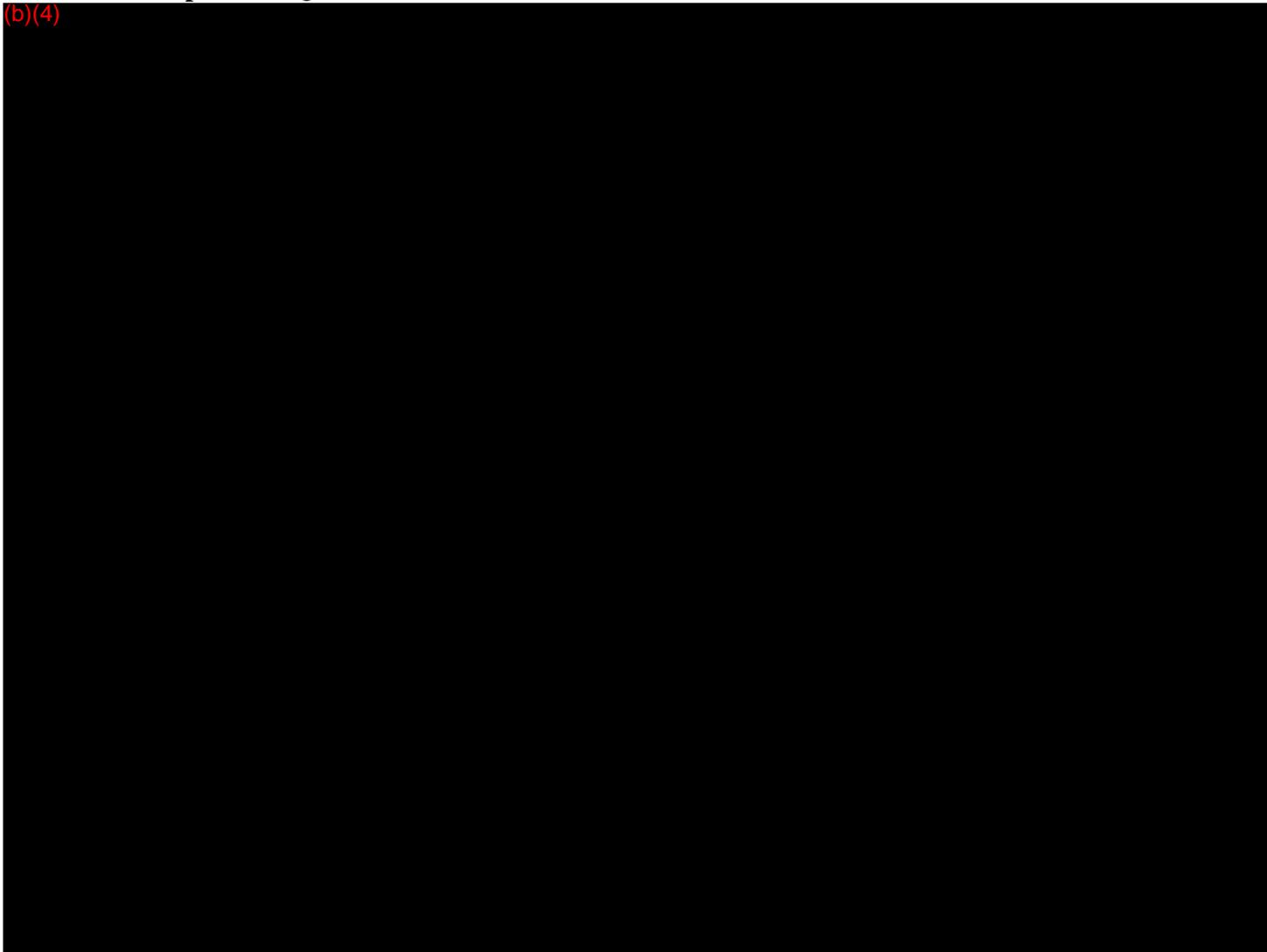
FDA Question 2

(b)(4)

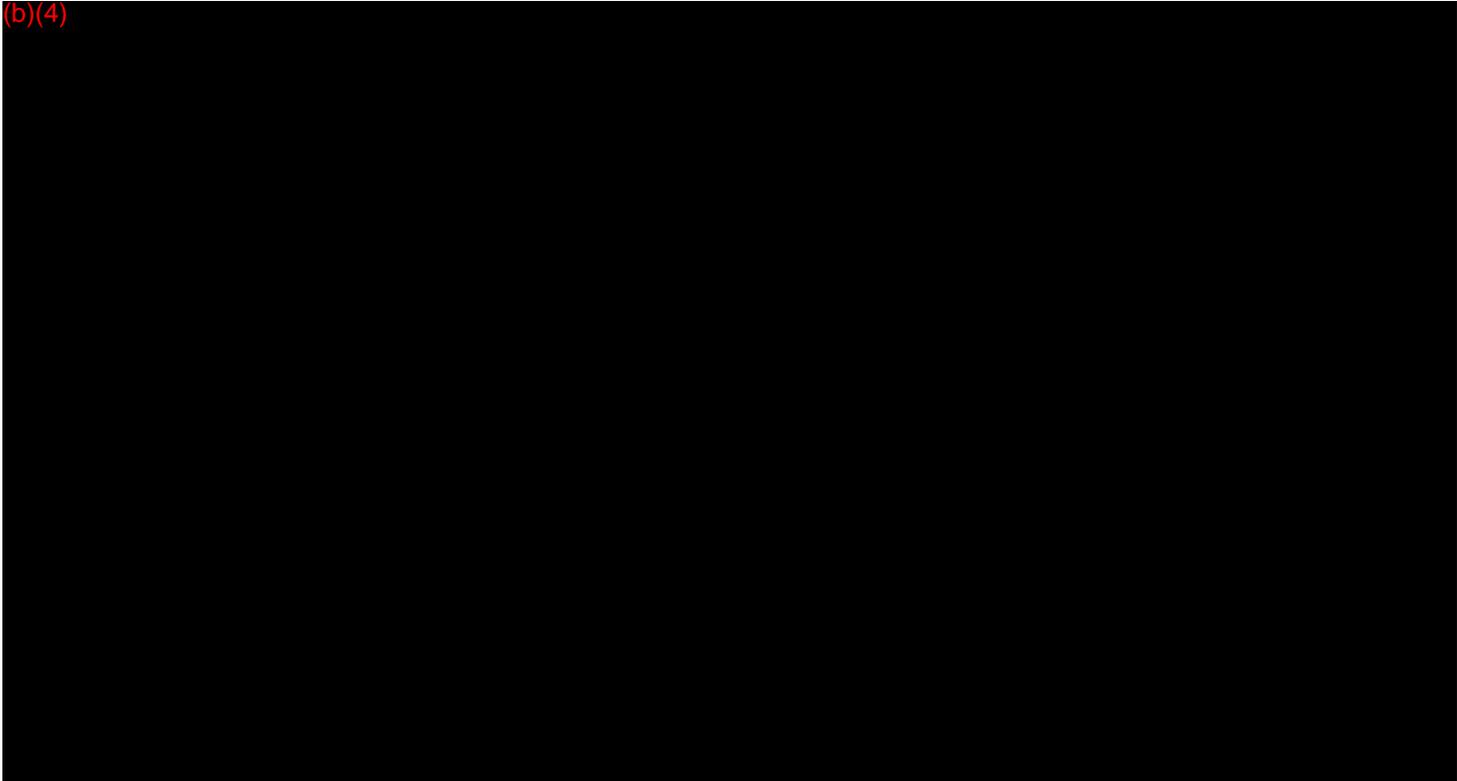
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SJM Response to Question 2

(b)(4)

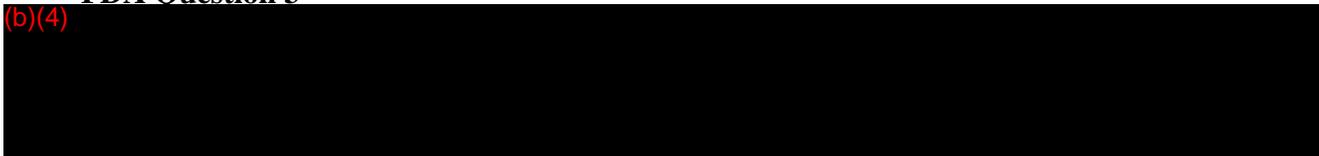
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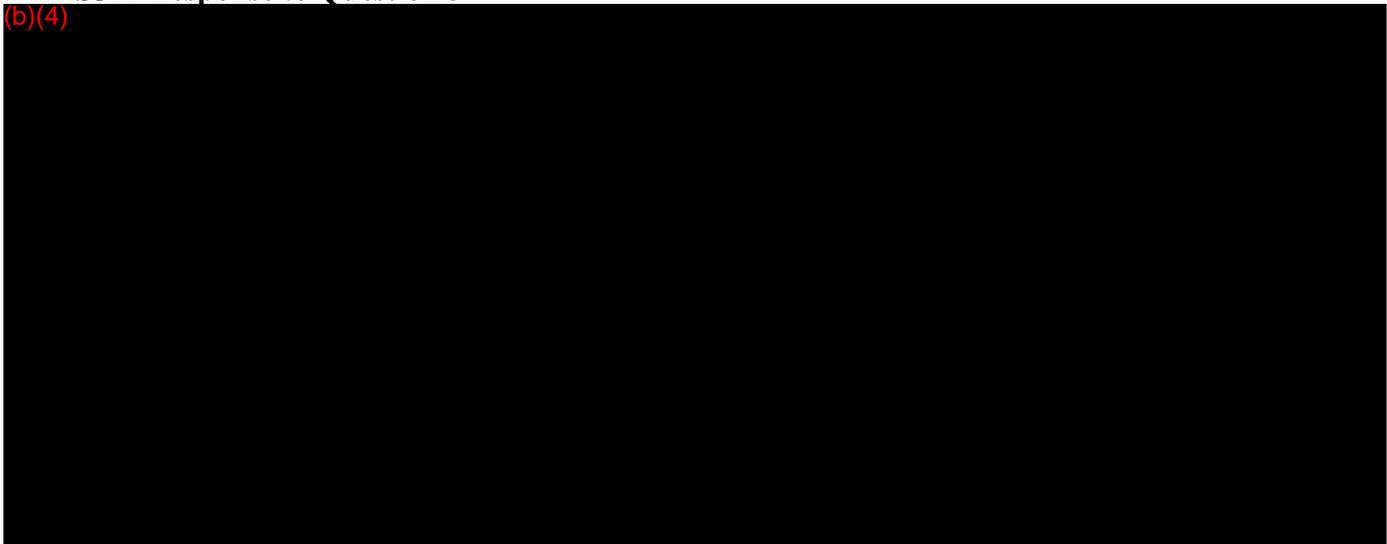
FDA Question 3

(b)(4)



SJM Response to Question 3

(b)(4)



(b)(4)



APPENDIX 1

Records processed under FOIA Request # 2015-3393; Released by CDRH on 09-23-2015

From: Lacy, Frank [Frank.Lacy@fda.hhs.gov]
Sent: Monday, March 26, 2012 8:21 AM
To: Canan, Colleen
Cc: Lacy, Frank
Subject: REVISED RE: K120298

Ms. Canan,

Please add the following question to the two listed below:

(
b
)

Thanks,
Frank Lacy

From: Lacy, Frank
Sent: Thursday, March 22, 2012 6:13 AM
To: 'ccanan@sjm.com'
Subject: K120298

Hi Ms. Canan,

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Regards,
Frank Lacy

March 22, 2012

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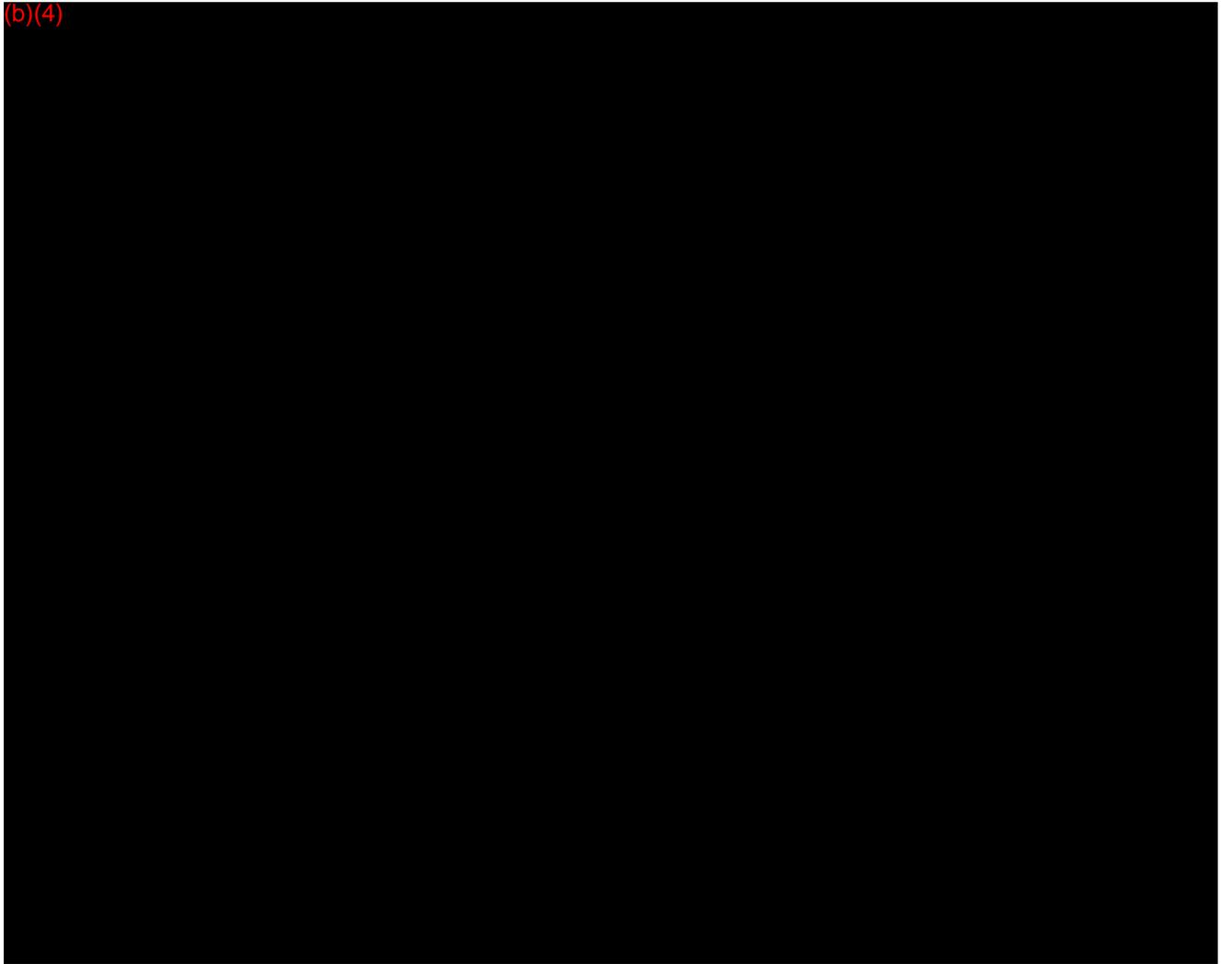
If you have any questions, please feel free to contact me via e-mail or at (301) 796-6321.

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Question(s) for the manufacturer:

(b)(4)

(b)(4)



Sincerely,
Frank Lacy; frank.lacy@fda.hhs.gov
Electrical Engineer
US Food and Drug Administration