



# U.S. Department of Health & Human Services

---

Food and Drug Administration

## SAVE REQUEST

**USER:** (kml)  
**FOLDER:** K043465 - 1112 pages  
**COMPANY:** SPECTRANETICS CORP. (SPECTRANETICS)  
**PRODUCT:** CATHETER FOR CROSSING TOTAL OCCLUSIONS (PDU)  
**SUMMARY:** Product: 2.5 MM TURBO CLIRPATH EXCIMER LASER CATHETER,  
MODEL 225-011  
**DATE REQUESTED:** Jul 26, 2016  
**DATE PRINTED:** Jul 26, 2016  
**Note:** Printed





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

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

SEP 18 2013

Re: K043465  
Trade/Device Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: PDU  
Dated: August 12, 2005  
Received: August 15, 2005

Dear Mr. Burris:

This letter corrects our substantially equivalent letter of August 18, 2005.

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 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 contact 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>. 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,



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

Enclosure

7. Statement of Indication for Use

Device Name: Spectranetics 2.5 mm Turbo™  
Excimer Laser Catheter

Indications for Use

For use in the endovascular treatment of symptomatic infringuinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

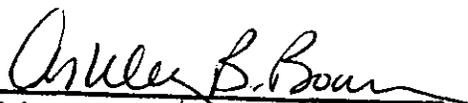
Prescription Use XXXX  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K043465

--- REMOVE SECTIONS BELOW THIS LINE WHEN PRINTING or EMAILING to SPONSORS ---

Full Submission Number: K043465

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off	

Template Name: Corrected Substantially Equivalent Letter: Classified and Not Classified;  
v2013-04-02

----- REMOVE BELOW WHEN USING TEMPLATE -----

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
9/25/12	Edwena Jones	Added digital signature format
12/12/2012	Margaret McCabe Janicki	One digit was missing from 4-digit ZIP code extension in letterhead ("002" should read "0002"). Revised to fix this.
04/02/2013	Sara Aguel	Clarified letter instructions; added OIR option in signature block. Added option for IVD labeling regulation. Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA. Added sentence that starts "Please note: CDRH does not evaluate information related to contract liability warranties..." to be consistent with language in K1(A) SE letter. Added instructions to "Re: [510(k) NUMBER]" section to be consistent with language in K1(A) SE letter.
4/12/2013	Margaret McCabe Janicki	Fixed typos in paragraph 1, final sentence: "We remind you; however, that...misleading" – replaced the incorrect semicolon with a comma and added a period at the end of the sentence.



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

Premarket Notification [510(k)] Review
Traditional/Abbreviated

Multiple 510(k)s Affected

Date: 8/26/2013
To: The Record
From: Todd Courtney

Office: ODE
Division: DCD

510(k) Holder: Multiple Companies
Device Name: Multiple Devices
Contact: Multiple Contacts

After discussion in the Peripheral Interventional Devices Branch (PIDB), we decided that a new product code should be created for chronic total occlusion (CTO) catheters. Previously these catheters had the following product codes: DQY, MCW and ITX. There were also changes to the regulations for some of the devices. The reasons for the changes to the existing product codes are as follows:

- The DQY product code is basically a generic product code used for percutaneous catheters. Since there has been an interest in CTO devices recently, PIDB decided to create a product code specifically for those devices, instead of continuing the practice of assigning them the generic percutaneous catheter product code (DQY).
The MCW product code is used for atherectomy devices and some of the devices in the below list were originally cleared with that product code. The Spectranetics devices were cleared with data and indications for use statements that are more typical of CTO devices and thus the reason for those changes. The Bard device was a CTO device that was inadvertently cleared through the 3rd party review process with "via atherectomy" in the indications for use statement and concurrently given the MCW product code. There was no data provided to support the change from a CTO device to an atherectomy device and FDA still believes it to be a CTO device.
As for the ITX product code, that code was originally used for devices that contained an imaging component to the CTO catheter. The 3 devices that are affected by that product code (K101777, K081804, & K072155) were all reviewed by PVDB, even though the product code database indicates that those devices would have a radiology classification advisory committee.

Table with 2 columns: Kxxxxxx, CTO Devices. Rows include: K123532 Avinger Ocelot Pixl Catheter, K123462 Avinger Ocelot Catheter, K122380 Avinger Ocelot Catheter, K120533 Covidien - Viance Crossing Catheter, Enteer Reentry System Catheter, Enteer Re-Entry System Guidewire, K120273 Kittycat, Kittycat 2, K113838 Wildcat Catheter



Kxxxxx	CTO Devices
K112308	Bard Crosser
K111338	Wildcat Catheter
K101777	Medtronic Pioneer Plus Catheter
K101615	Baylis Power Wire RF Guidewire
K101599	Boston Scientific TruePath CTO
K092175	Bard Crosser System
K091119	Bard Crosser System
K083814	Cordis Outback LTD Re-Entry Catheter
K082143	Cordis Micro Guide Catheter
K081804	Medtronic Pioneer Plus Catheter
K072776	Bard (FlowCardia) Crosser System
K072155	Medtronic Pioneer Plus Catheter
K071227	CLiRpath Turbo and Turbo Elite Excimer Laser Catheters
K071226	8 Fr and 7Fr Turbo Booster Guiding Catheters
K060012	CLiRpath Turbo Peripheral Catheter
K052514	CLiRpath Turbo Plus Excimer Laser Catheter
K052296	CLiRpath Turbo Excimer Laser Catheter
K051670	Baylis RF Tunneler Wire
K050916	Safe-Cross Radio Frequency Total Occlusion Crossing System
K043465	2.5 Mm Turbo CLiRpath Excimer Laser Catheter
K040067	CLiRpath Excimer Laser Catheter
K033535	LuMend Frontrunner CTO Catheter
K031842	Safe-Cross Radio Frequency Total Occlusion Crossing System
K031005	LuMend Frontrunner CTO Catheter
K023114	LuMend Frontrunner CTO Catheter

John Canty 8/26/2013  
 Reviewer/Date

Z.M.Z. 8/26/13  
 Branch Chief/Date



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

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

SEP 18 2013

Re: K043465

Trade/Device Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: PDU  
Dated: August 12, 2005  
Received: August 15, 2005

Dear Mr. Burris:

This letter corrects our substantially equivalent letter of August 18, 2005.

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 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 contact 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>. 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,



*for*

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

Enclosure

7. Statement of Indication for Use

Device Name: Spectranetics 2.5 mm Turbo™  
Excimer Laser Catheter

Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Prescription Use XXXX  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arthur B. Bour  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K043465

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

Official Business  
Penalty for Private Use, \$300



UNITED STATES POSTAGE  
PRIMEV BOWES  
02 1M \$00.460  
0004269858 SEP 23 2013  
MAILED FROM ZIP CODE 02203

NIXIE 802 FE 1009 0009/28/13

RETURN TO SENDER  
NOT DELIVERABLE AS ADDRESSED  
UNABLE TO FORWARD

BC: 26963165899 #0231-02878-23-44

8090743159 050958

AUG 18 2005

## 510(k) SUMMARY

### SUBMITTER INFORMATION

- A. Company Name: Spectranetics Corporation, Inc.
- B. Company Address: 96 Talamine Court  
Colorado Springs, Colorado 80907
- C. Company Phone: 719-633-8333 / 1-800-633-0960
- D. Company Facsimile: 719 442 2248
- E. Contact Person: Adrian Elfe  
Vice President  
Quality Assurance & Regulatory Affairs Compliance

### DEVICE IDENTIFICATION

- A. Device Trade Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter
- B. Device Common Name: Laser Catheter
- C. Classification Name: Catheter, Peripheral, Atherectomy
- D. Device Class: Class II (per 21 CFR 870.4875)
- E. Device Code: MCW

### IDENTIFICATION OF PREDICATE DEVICES

Spectranetics CLiRpath excimer laser catheters for peripheral use, cleared to market under 510(k) K040067, serve as predicate to the 2.5 mm Turbo CLiRpath Excimer Laser Catheter.

## DEVICE DESCRIPTION

Spectranetics' laser atherectomy catheters, including the 2.5 mm Turbo CLiRpath catheter for peripheral use, consist of a bundle of optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from a source to the tip of the catheter. The catheter is inserted into a patient's vasculature along the length of a previously inserted medical guidewire, allowing the attending physician to deliver laser energy targeted to a lesion (blockage) in the blood vessel. The 2.5 mm Turbo catheter is designed for "over-the-wire" interventional techniques. Laser energy impinged on a blockage ablates, or debulks, the lesion material re-establishing blood flow within the vessel, and permitting placement of devices used in vascular interventions.

The Spectranetics Turbo laser catheter is supplied with a tip diameter of 2.5 mm, appropriate for interventional use in the peripheral vasculature of the leg.

## INTENDED USE

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

## COMPARISON TO PREDICATE DEVICES

The Spectranetics 2.5 mm Turbo Excimer Laser Catheter for peripheral use is substantially equivalent in form, fit, and function to other Spectranetics CLiRpath laser catheters, which received market clearance under section 510(k) rules. The 2.5 mm Turbo catheter is an addition to the CLiRpath line of catheters, with the following enhancements.

- Increased lubricity
- Improved efficiency in energy delivery of 308 nm laser light
- Continuous "on" capability

The 2.5 mm Turbo laser catheter consists of a piece of tubing with a working length of approximately 110 cm, and a diameter of 2.5 mm. The catheters communicate excimer laser energy at 308 nm to an occlusion within a patient's targeted peripheral artery. Communicated energy disrupts occlusive material, such as arterial plaque, and permits its removal via the patient's endoreticular system. The pathway opened by either the predicate device or the Turbo catheter, facilitates subsequent placement of other devices and interventions, and re-establishes blood flow within the diseased vessel.

## **BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING**

Biocompatibility of both component materials and the finished 2.5 mm Turbo catheter have been confirmed in accord with the ISO 10993 series of standards, Biological Evaluation of Medical Devices. Spectranetics conducts and maintains valid ethylene oxide sterilization processes in accord with ISO 11135, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. Package integrity is initially validated, and, in addition, visually verified for 100% of Spectranetics devices prior to transfer to finished goods inventory.

Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. All CLiRpath excimer laser catheter models meet or exceed both Spectranetics in-house requirements, and requirements listed in ISO 10555-1, Sterile, Single-use Intravascular Catheters – Part 1: General Requirements.

## **NON-CLINICAL STUDIES**

Spectranetics confirmed safety and equivalent efficacy in the peripheral anatomy for the 2.5 mm Turbo laser catheter using a porcine model, in accord with a protocol compliant with good laboratory practices (GLP's). No complications were noted during treatment of the iliac and femoral arteries in the animal model. Histological evaluation of harvested arterial segments showed no deleterious tissue damage after exposure to the 2.5 mm Turbo catheter operating at maximum energy parameters. Comparisons to treatment with CLiRpath laser catheters, the cited predicate device, indicated that the 2.5 mm Turbo catheter was equivalent with respect to both safety and functionality.

## **CONCLUSION**

A GLP-compliant study using a porcine model verified the safety and performance characteristics for the Spectranetics 2.5 mm Turbo laser catheter when deployed for use in the treatment of peripheral arterial disease. In vitro laboratory tests, as well as qualification and validation studies, have confirmed that 2.5 mm Turbo catheters meet manufacturing and design specifications. All of these data combined establish substantial equivalence to the CLiRpath predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 18 2005

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

Re: K043465  
2.5 mm Turbo CLiRpath Excimer Laser Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Peripheral Atherectomy Catheter  
Regulatory Class: Class II  
Product Code: MCW  
Dated: August 12, 2005  
Received: August 15, 2005

Dear Mr. Burris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Neil Burris

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

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

Enclosure

K043465

7. Statement of Indication for Use

Device Name: Spectranetics 2.5 mm Turbo™  
Excimer Laser Catheter

Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Prescription Use XXXX  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K043465



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 18 2005

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

Re: K043465  
2.5 mm Turbo CLiRpath Excimer Laser Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Peripheral Atherectomy Catheter  
Regulatory Class: Class II  
Product Code: MCW  
Dated: August 12, 2005  
Received: August 15, 2005

Dear Mr. Burris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Neil Burris

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

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

Enclosure

7. Statement of Indication for Use

Device Name: Spectranetics 2.5 mm Turbo™  
Excimer Laser Catheter

Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

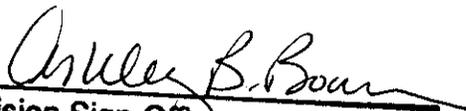
Prescription Use XXXX  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K043465



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

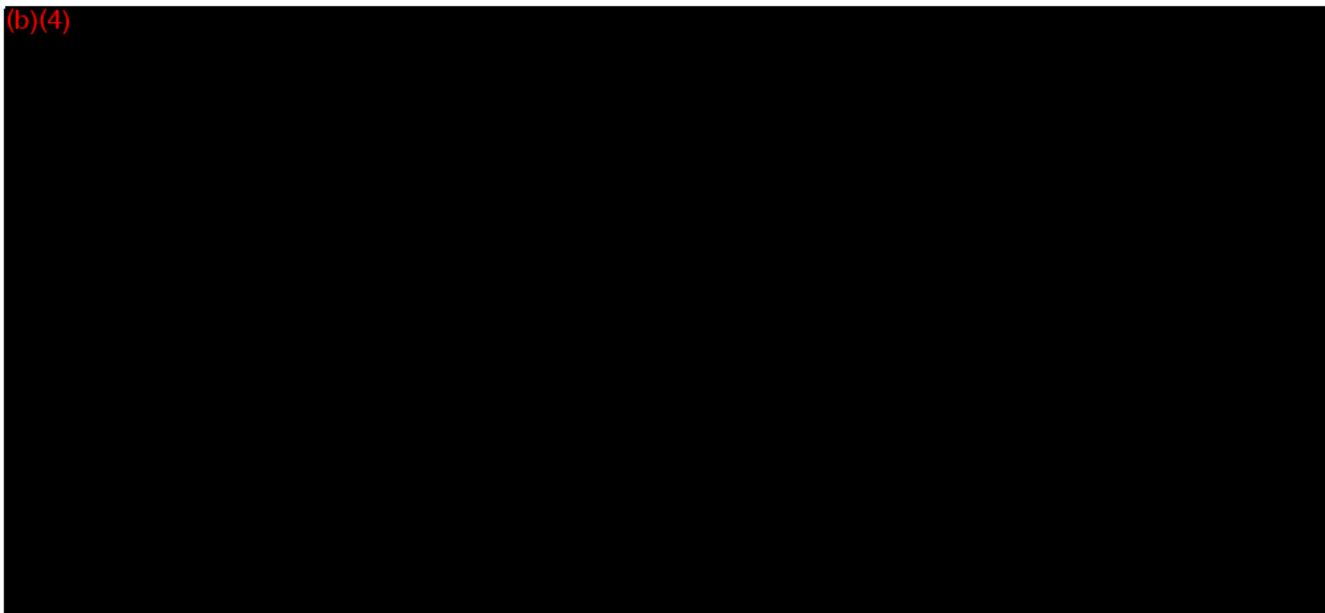
AUG 3 2005

Re: K043465  
Trade Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter  
Dated: June 30, 2005  
Received: July 1, 2005

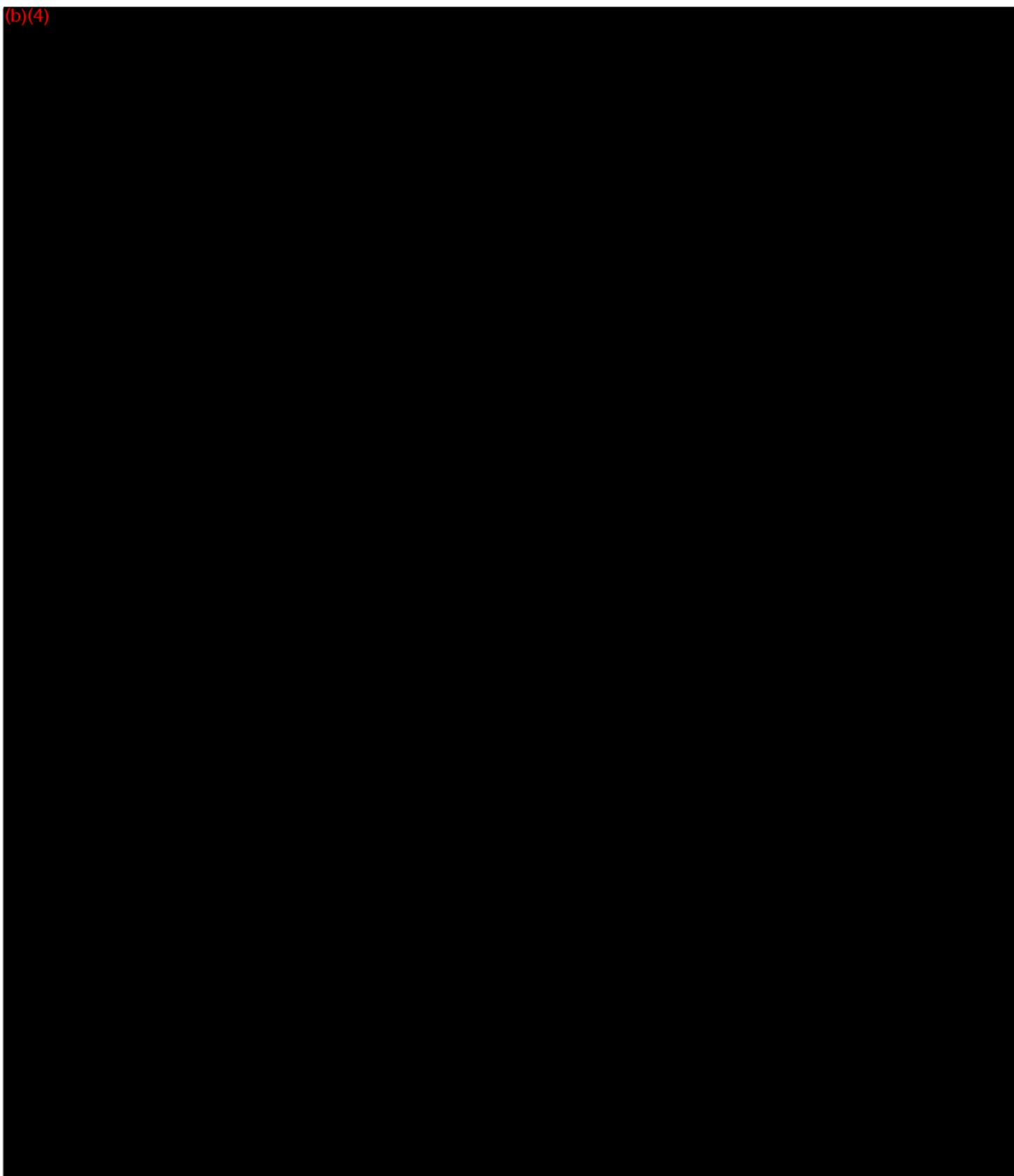
Dear Mr. Burris:

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

(b)(4)



(b)(4)



The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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". 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/cdrh/mdufma/guidance/1219.html>.

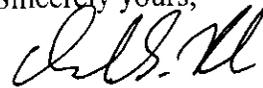
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

Page 4 - Mr.Neil Burris

If you have any questions concerning the contents of the letter, please contact Dr. Kenneth Cavanaugh at (301) 443-8517, extension 170. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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

AUG -3 2005

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

Re: K043465

Trade Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter

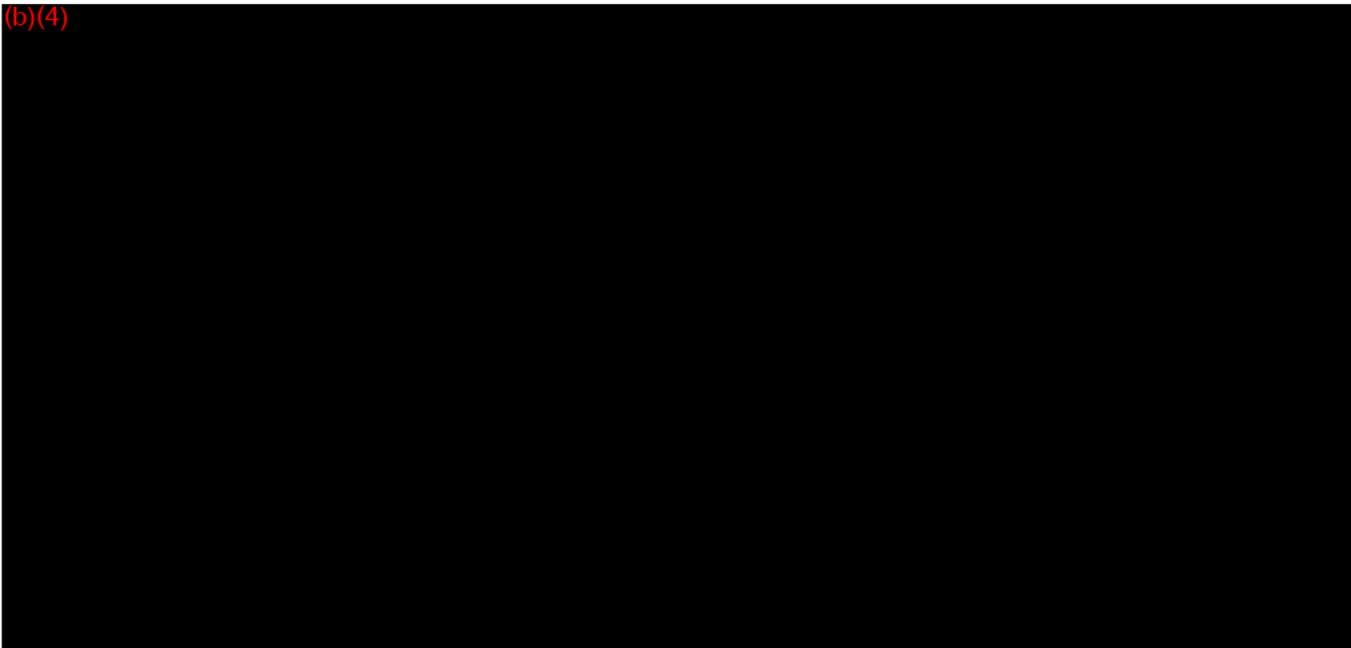
Dated: June 30, 2005

Received: July 1, 2005

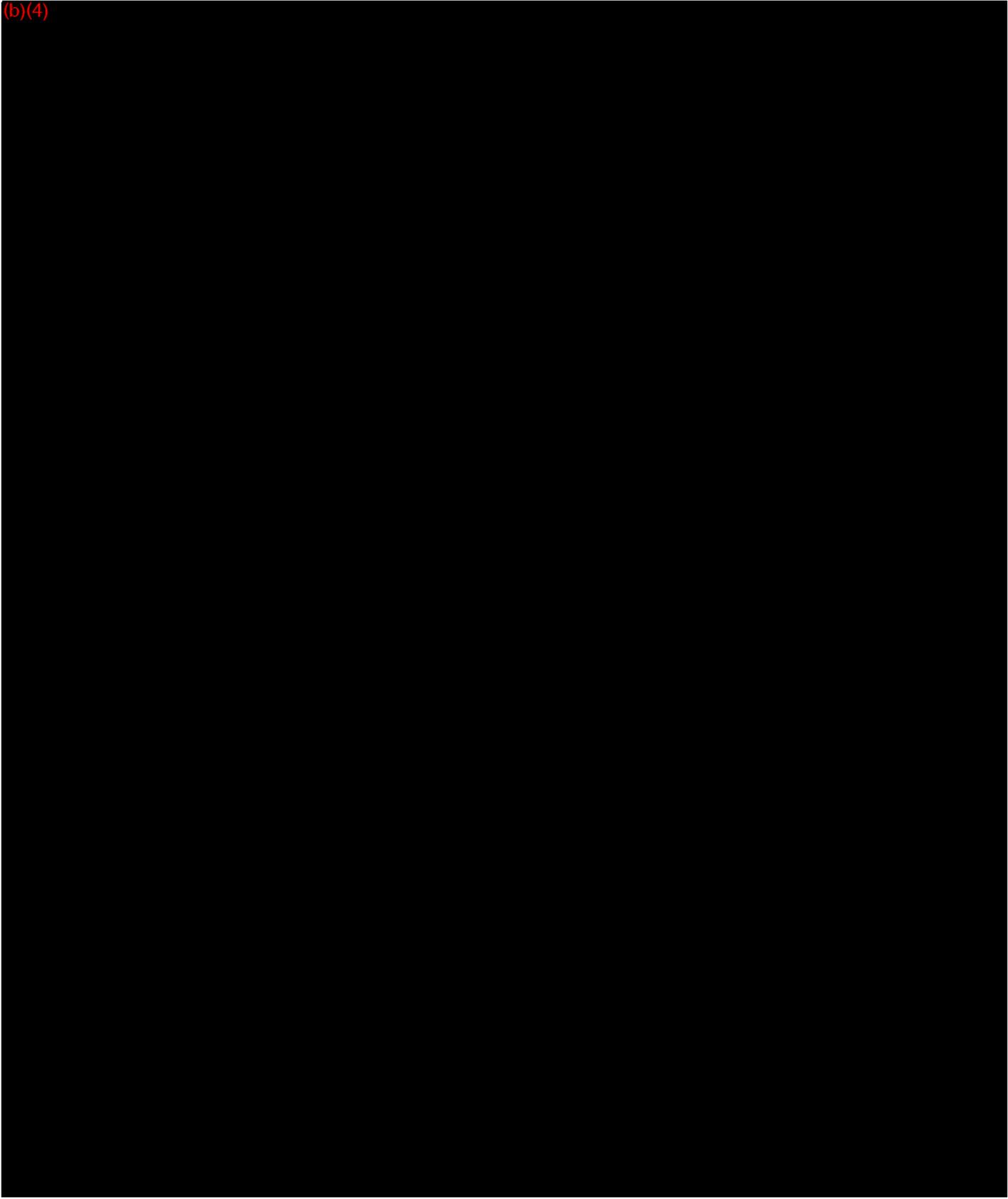
Dear Mr. Burris:

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

(b)(4)



(b)(4)



The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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". 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/cdrh/mdufma/guidance/1219.html>.

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

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

Page 4 - Mr.Neil Burris

If you have any questions concerning the contents of the letter, please contact Dr. Kenneth Cavanaugh at (301) 443-8517, extension 170. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

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

Page 5 - Mr.Neil Burris

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ- Division  
D.O.

Prepared by: KJCavanaugh:bmw07/29/05

# FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

JAN 31 2005

Re: K043465

Trade Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter

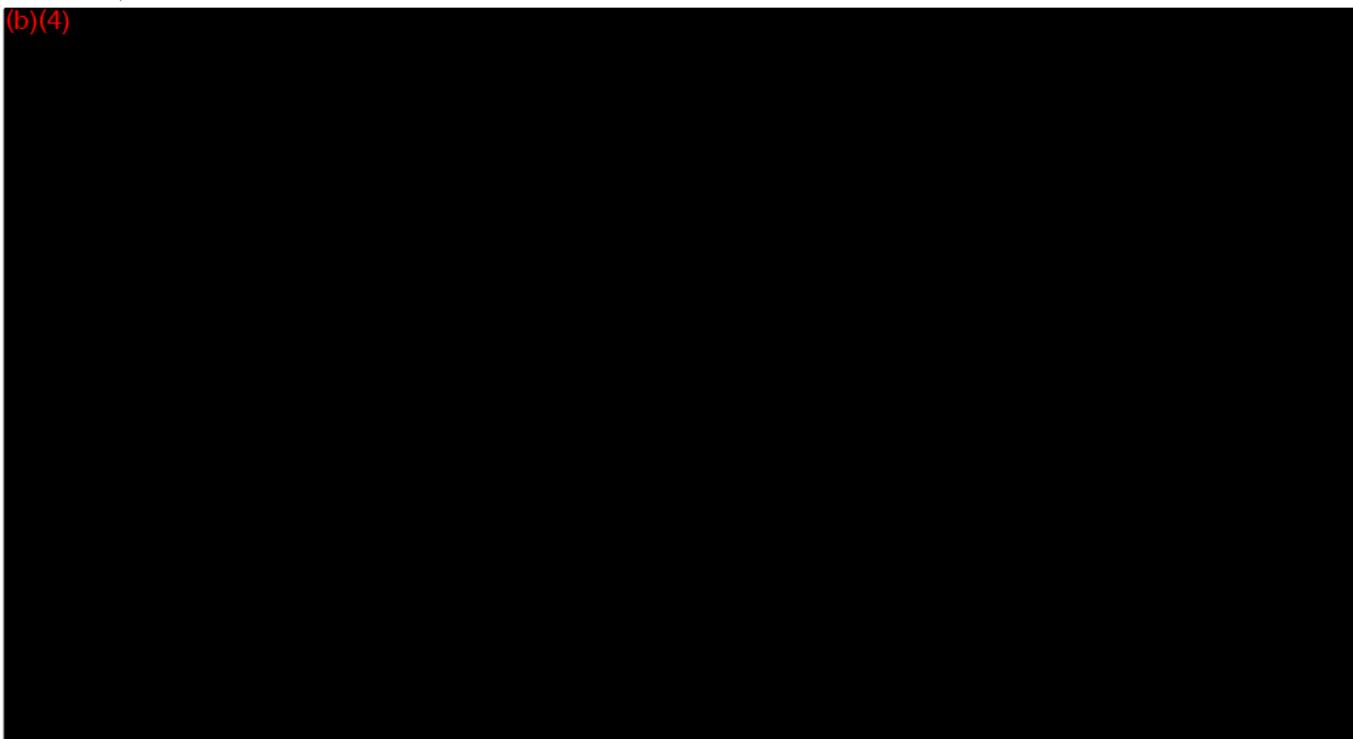
Dated: December 13, 2004

Received: December 15, 2004

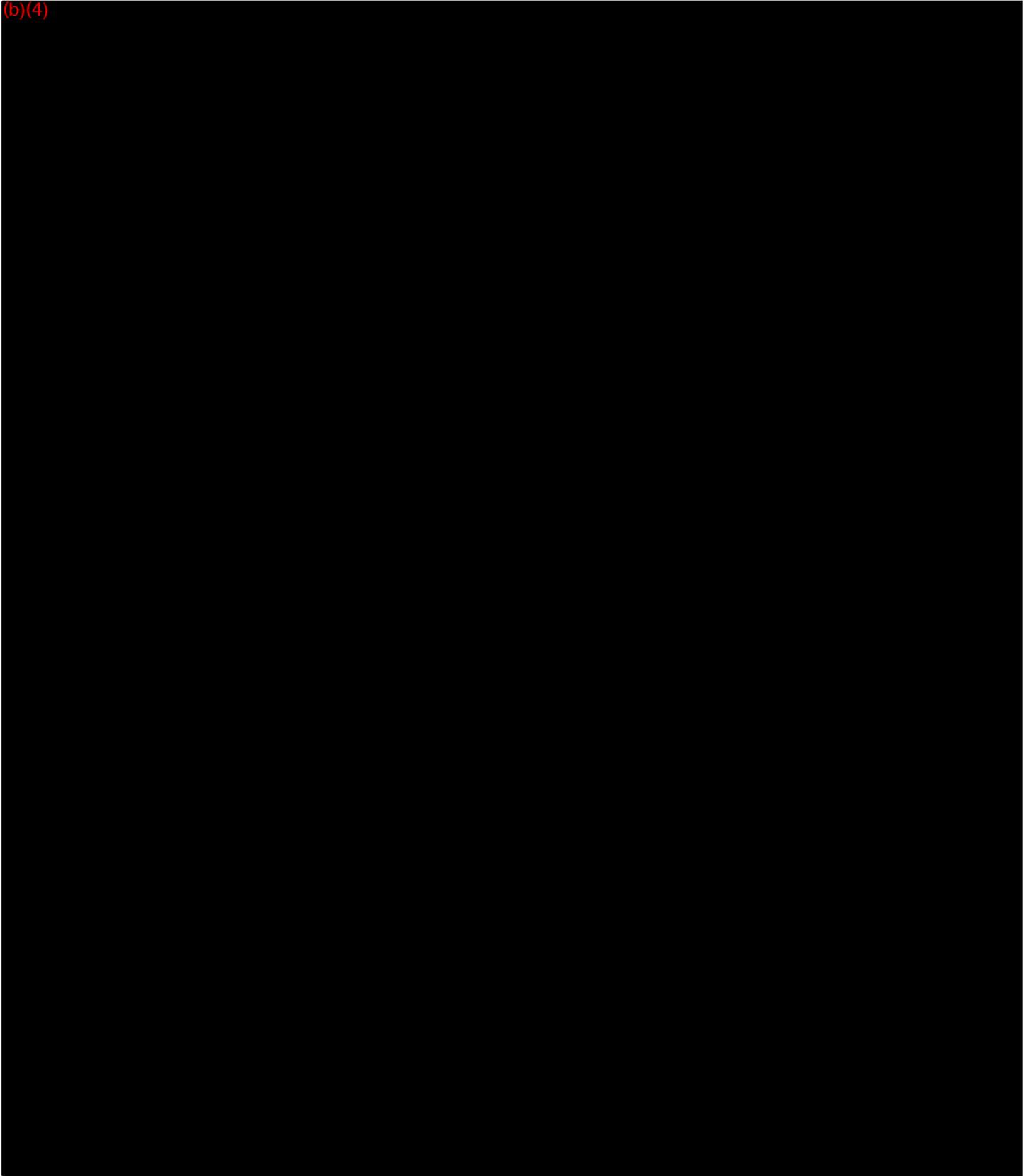
Dear Mr. Burris:

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

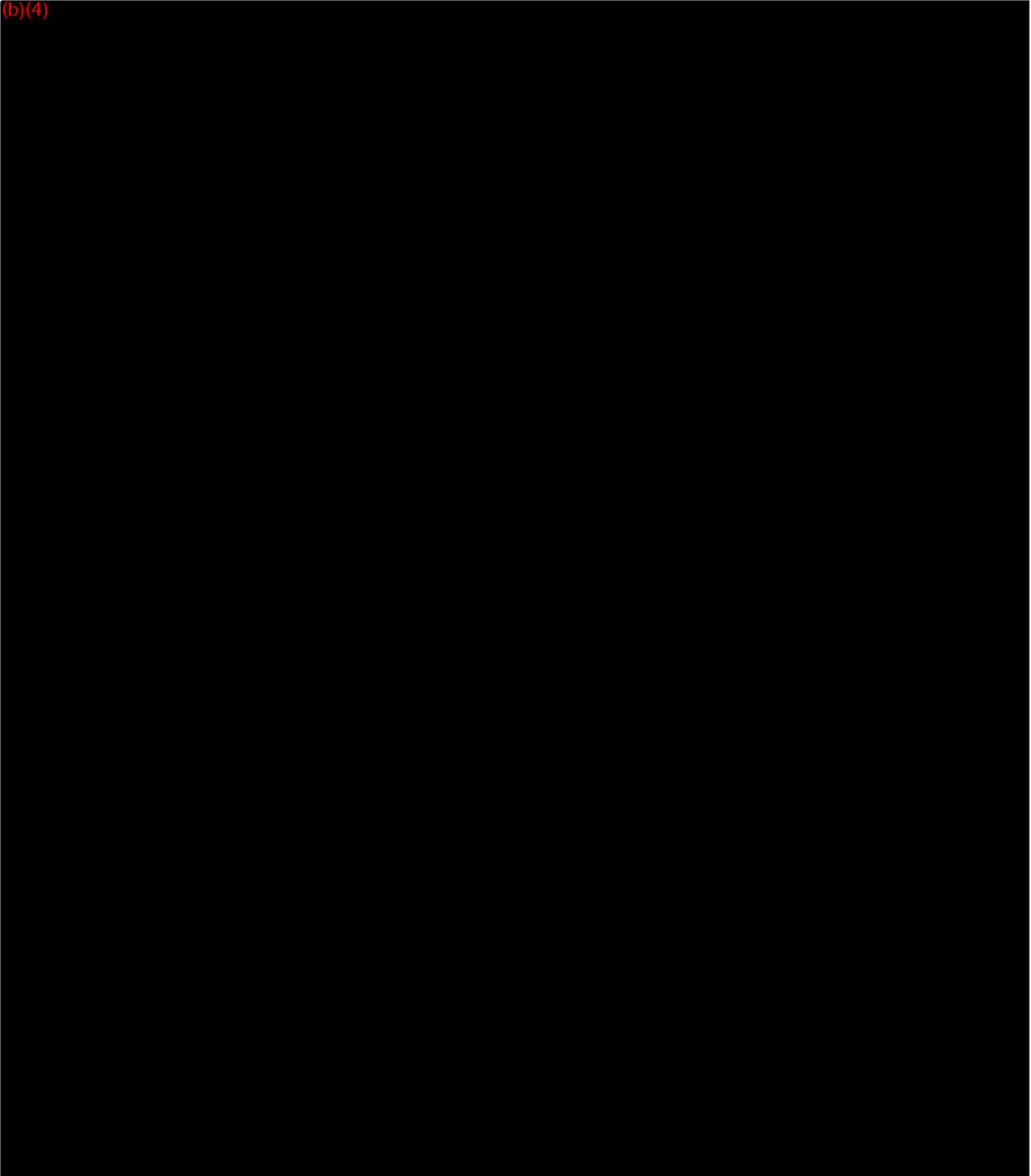
(b)(4)



(b)(4)



(b)(4)



(b)(4)



The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

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

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

Page 5 – Mr. Neil Burris

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/cdrh/mdufma/guidance/1219.html>.

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

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

If you have any questions concerning the contents of the letter, please contact Dr. Kenneth Cavanaugh at (301) 443-8517, extension 170. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Handwritten signature of Bram D. Zuckerman in cursive, followed by the word "FOR" in capital letters.

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

Spectranetics Corporation  
c/o Mr. Neil Burris  
Clinical Data Services  
96 Talamine Court  
Colorado Springs, CO 80907

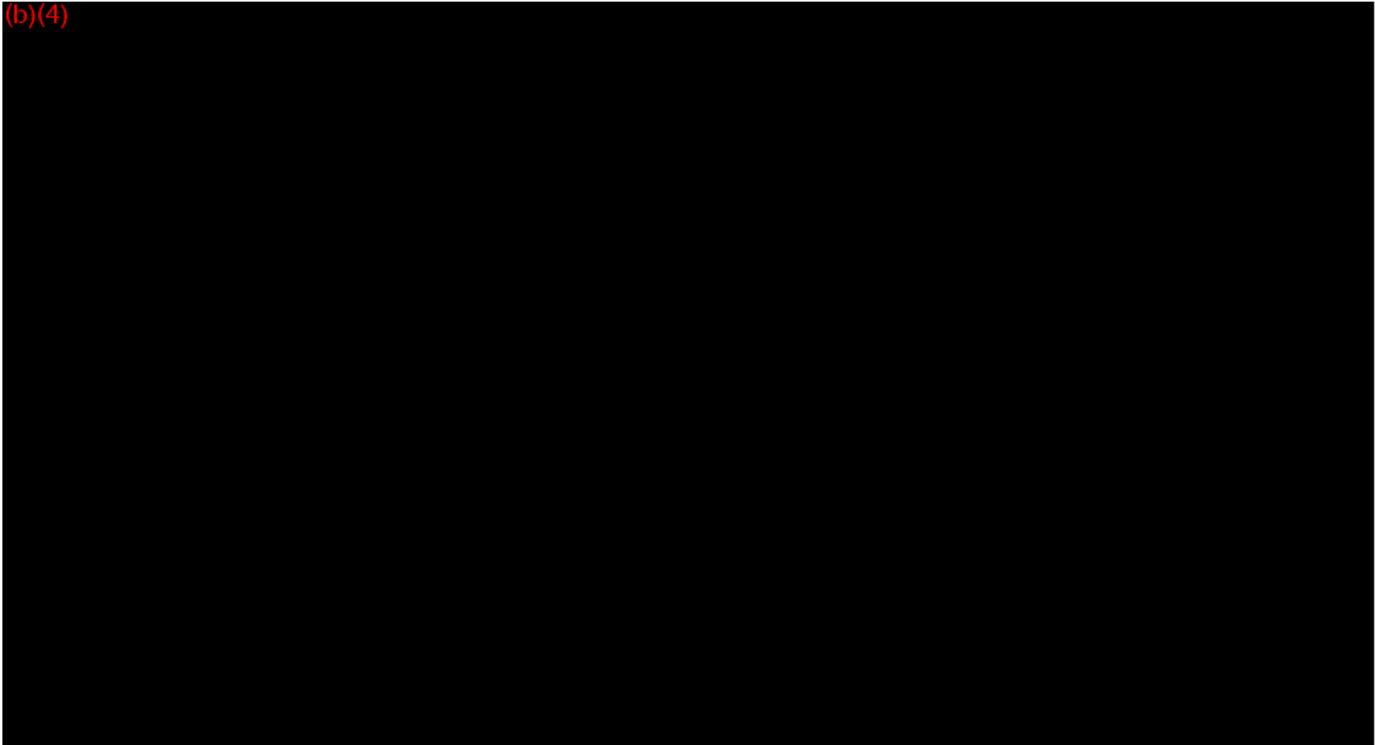
DEC 31 2004

Re: K043465  
Trade Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter  
Dated: December 13, 2004  
Received: December 15, 2004

Dear Mr. Burris:

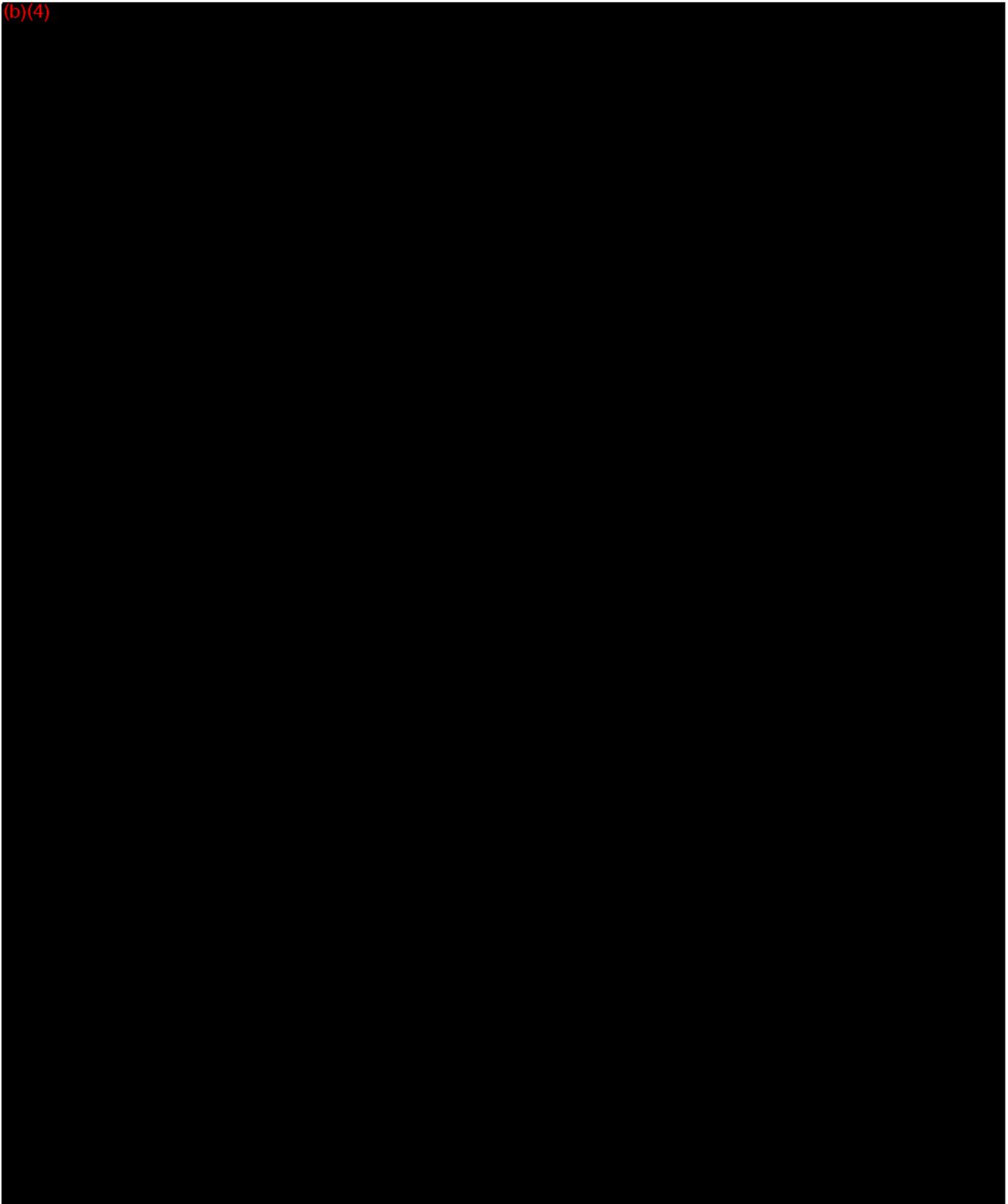
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we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

(b)(4)

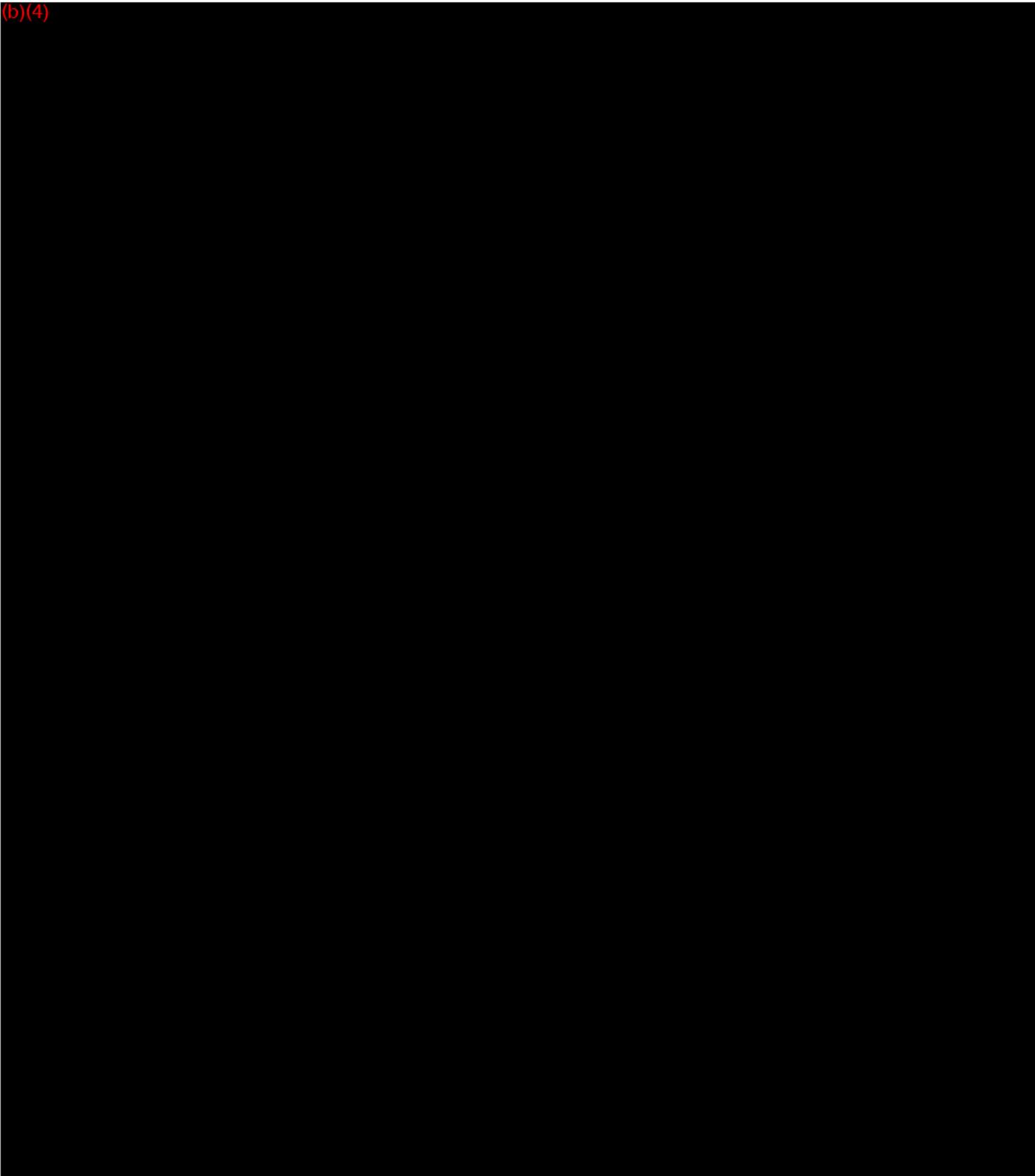


819

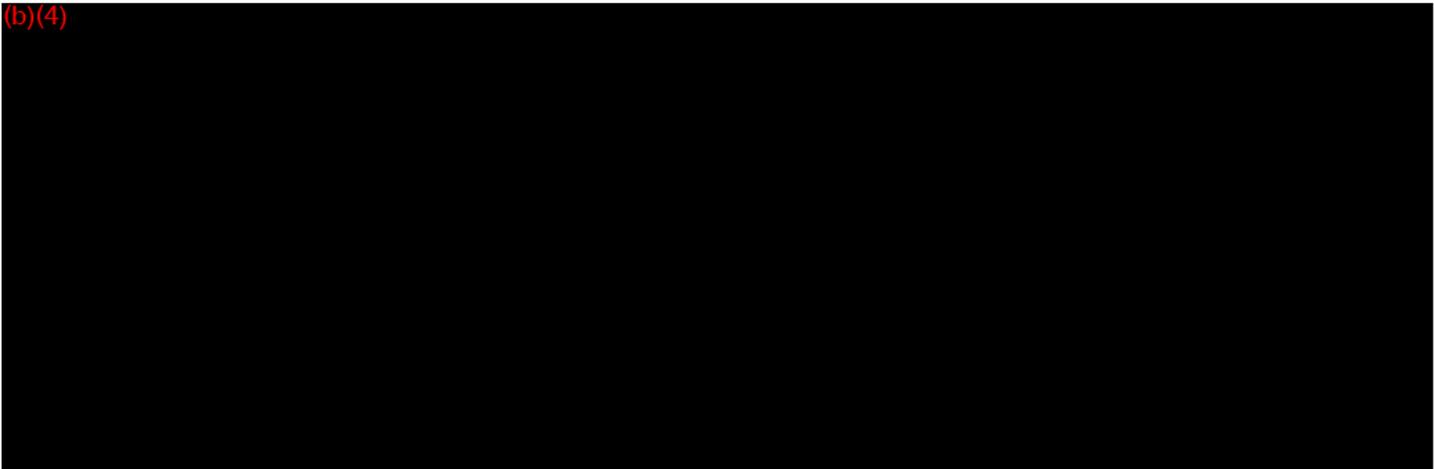
(b)(4)



(b)(4)



(b)(4)



The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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”. 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/cdrh/mdufma/guidance/1219.html>.

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

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

If you have any questions concerning the contents of the letter, please contact Dr. Kenneth Cavanaugh at (301) 443-8517, extension 170. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

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

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ-450 DCD  
D.O.

Final: Linda Bessacque: 01/28/05

# FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-450	Cavanagh	1/28/05			
2-450	Bessacque	1/31/05			

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

December 21, 2004

SPECTRANETICS CORP.  
96 TALAMINE CT.  
COLORADO SPRINGS, CO 80907  
ATTN: ADRIAN E. ELFE

510(k) Number: K043465  
Received: 15-DEC-2004  
Product: 2.5 MM TURBO  
CLIRPATH EXCIMER  
LASER CATHETER,  
MODEL 225-011

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

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 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 [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

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

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

December 16, 2004

SPECTRANETICS CORP.  
96 TALAMINE CT.  
COLORADO SPRINGS, CO 80907  
ATTN: ADRIAN E. ELFE

510(k) Number: K043465  
Received: 15-DEC-2004  
Product: 2.5 MM TURBO  
User Fee ID Number: 165564CIMER  
LASER CATHETER,

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

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier (e.g., Fed Ex, UPS, etc.)

-----  
Food and Drug Administration  
P.O. Box 956733  
St. Louis, MO 63195-6733.

-----  
U.S. Bank  
956733  
1005 Convention Plaza  
St. Louis, MO 63101  
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

# Spectranetics<sup>®</sup>

we get your blood flowing<sup>™</sup>

K 043465

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

13 December 2004

Re: **Premarket Notification 510(k) Submission**  
**2.5 mm Turbo CLiRpath<sup>™</sup> Excimer Laser Catheter (model 225-011)**

Dear Staff,

Spectranetics submits this Premarket Notification for an addition to the CLiRpath peripheral excimer laser atherectomy product line, the 2.5 mm Turbo excimer laser catheter (model 225-011). CLiRpath<sup>™</sup> Excimer Laser Catheters are Class II devices for use in treating atherosclerotic occlusions in the legs.

This notification requests clearance to expand the current CLiRpath product offering from seventeen (17) laser catheter models to eighteen (18) models, with the addition of the 2.5 mm Turbo catheter. CLiRpath excimer laser catheters were initially cleared on 27 April 2004, under 510(k) number K040067.

The redesigned 2.5 mm Turbo catheter incorporates three (3) enhancements not available in the current CLiRpath product offering:

- Increased lubricity and tractability;
- Increased optical fiber count; and
- Continuous "on" capability (no software enforced "laser off" time).

The enhancements improve handling, and ease use, of the catheter by physicians.

Evidence of safety equivalent to the previously approved 2.5 mm Extreme II CLiRpath catheter was gathered using an animal (porcine) model. Spectranetics is providing the resultant data from the study, which was carried out in compliance with Good Laboratory Practices.

The Spectranetics Corporation, 96 Talamine Court, Colorado Springs, CO 80907, is the address for both the manufacturing and sterilization site for the Spectranetics Catheters.

One original and two copies of this Premarket Notification are enclosed. We respectfully request protection provided by law for confidential commercial information or trade secrets. If further information is required, please contact Neil Burris at 719-442-2456 [FAX 719-442-2481], or Adrian E. Elfe at 719-442-2425.

Sincerely yours,



Neil Burris  
Clinical Data Services

CV #  
sk 3

Coronary Artery  
Disease Therapy

Cardiac Lead  
Removal Systems

Peripheral Vascular  
Disease Therapy

CVX 300  
Excimer Technology

THE SPECTRANETICS CORPORATION  
96 Talamine Court  
Colorado Springs, CO 80907-5186  
Tel: 719-633-8333  
Customer Service: Tel: 800-231-0978  
Fax: 719-633-8791

www.spectranetics.com

8418

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

Date of Submission: **13 Dec 04**

FDA Document Number:

**Section A**

**Type of Submission**

- |   |   |  |   |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k)        | <input type="checkbox"/> IDE            | <input type="checkbox"/> PMA           | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment  | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
|   | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report    | <input type="checkbox"/> PMA Supplement - 30 day  |
|   | <input type="checkbox"/> IDE Report     |  | <input type="checkbox"/> PMA Supplement - Panel   |

Track

**Section B1**

**Reason for Submission  510(k)s Only**

- |  |   |  |
|--|---|--|
| <input checked="" type="checkbox"/> New device   | <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other reason (specify): |   |  |

**Section B2**

**Reason for Submission  PMAs Only**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> New device                         | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change:    |
| <input type="checkbox"/> Withdrawal                         | <input type="checkbox"/> Software                                       | <input type="checkbox"/> Manufacturer        |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive                                 | <input type="checkbox"/> Sterilizer          |
| <input type="checkbox"/> Licensing agreement                | <input type="checkbox"/> Other (specify below)                          | <input type="checkbox"/> Packager            |
| <input type="checkbox"/> Labeling change:                   | <input type="checkbox"/> Process change:                                | <input type="checkbox"/> Report submission:  |
| <input type="checkbox"/> Indications                        | <input type="checkbox"/> Manufacturer                                   | <input type="checkbox"/> Annual or periodic  |
| <input type="checkbox"/> Instructions                       | <input type="checkbox"/> Sterilizer                                     | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics        | <input type="checkbox"/> Packager                                       | <input type="checkbox"/> Adverse reaction    |
| <input type="checkbox"/> Shelf life                         |   | <input type="checkbox"/> Device defect       |
| <input type="checkbox"/> Trade name                         | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment           |
| <input type="checkbox"/> Other (specify below)              | <input type="checkbox"/> Request for applicant hold                     |  |
| <input type="checkbox"/> Change in ownership                | <input type="checkbox"/> Request for removal of applicant hold          |  |
| <input type="checkbox"/> Change in correspondent            | <input type="checkbox"/> Request for extension                          |  |
| <input type="checkbox"/> Other reason (specify):            | <input type="checkbox"/> Request to remove or add manufacturing site    |  |

**Section B3**

**Reason for Submission  IDEs Only**

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> New device                     | <input type="checkbox"/> Change in:                | <input type="checkbox"/> Response to FDA letter concerning:          |
| <input type="checkbox"/> Addition of institution        | <input type="checkbox"/> Correspondent             | <input type="checkbox"/> Conditional approval                        |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design                    | <input type="checkbox"/> Deemed approved                             |
| <input type="checkbox"/> IRB certification              | <input type="checkbox"/> Informed consent          | <input type="checkbox"/> Deficient final report                      |
| <input type="checkbox"/> Request hearing                | <input type="checkbox"/> Manufacturer              | <input type="checkbox"/> Deficient progress report                   |
| <input type="checkbox"/> Request waiver                 | <input type="checkbox"/> Manufacturing             | <input type="checkbox"/> Deficient investigator report               |
| <input type="checkbox"/> Termination of study           | <input type="checkbox"/> Protocol & feasibility    | <input type="checkbox"/> Disapproval                                 |
| <input type="checkbox"/> Withdrawal of application      | <input type="checkbox"/> Protocol & other          | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect   | <input type="checkbox"/> Sponsor                   | <input type="checkbox"/> Request meeting                             |
| <input type="checkbox"/> Emergency use:                 | <input type="checkbox"/> Report submission:        | <input type="checkbox"/> IOL submissions only:                       |
| <input type="checkbox"/> Notification of emergency use  | <input type="checkbox"/> Current investigator      | <input type="checkbox"/> Change in IOL style                         |
| <input type="checkbox"/> Additional information         | <input type="checkbox"/> Annual progress           | <input type="checkbox"/> Request for protocol waiver                 |
|   | <input type="checkbox"/> Site waiver limit reached |  |

FDA Document Number:

Section C

Product Classification

Product code:

MCW

C.F.R. Section:

21 CFR 870.4875

Device class:

Class I

Class II

Class III

Unclassified

Classification panel:

CARDIOVASCULAR

Section D

Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:

510(k) summary attached

510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K040067	1 CLIRpath EXCIMER LASER CATHETERS	SPECTRANETICS CORP.
2	2	2
3	3	3
4	4	4
5	5	5
6	8	8

Section E

Product Information:  Applicable to All Applications

Common or usual name or classification name:

Trade or proprietary or model name	Model number
1 2.5 mm Turbo CLIRpath EXCIMER LASER CATHETER	1 225-011
2	2
3	3
4	4
5	5
6	6

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

1 P410001	2 K040067	3	4	5	6
7	8	9	10	11	12

Data included in submission:

Laboratory testing

Animal trials

Human trials

Indications (from labeling):

FOR USE IN THE ENDOVASCULAR TREATMENT OF SYMPTOMATIC INFRAINGUINAL LOWER EXTREMITY VASCULAR DISEASE WHERE TOTAL OBSTRUCTIONS CAN NOT BE CROSSED WITH STANDARD GUIDE WIRES.

FDA Document Number:

**Section F Manufacturing / Packaging / Sterilization Sites**

Original  Add  Delete      FDA establishment registration number: 1721279       Manufacturer  Contract manufacturer       Contract sterilizer  Repackager / relabeler

Company / Institution name: SPECTRANETICS CORPORATION

Division name (if applicable): \_\_\_\_\_      Phone number (include area code): (719) 633 8333

Street address: 96 TALAMINE COURT      FAX number (include area code): (719) 442 2481

City: COLO SPRINGS      State / Province: CO      Country: USA      ZIP / Postal Code: 80907

Contact name: NEIL BARRIS

Contact title: CLINICAL DATA SERVICES

Original  Add  Delete      FDA establishment registration number:       Manufacturer  Contract manufacturer       Contract sterilizer  Repackager / relabeler

Company / Institution name:

Division name (if applicable): \_\_\_\_\_      Phone number (include area code): ( )

Street address: \_\_\_\_\_      FAX number (include area code): ( )

City: \_\_\_\_\_      State / Province: \_\_\_\_\_      Country: \_\_\_\_\_      ZIP / Postal Code: \_\_\_\_\_

Contact name:

Contact title:

Original  Add  Delete      FDA establishment registration number:       Manufacturer  Contract manufacturer       Contract sterilizer  Repackager / relabeler

Company / Institution name:

Division name (if applicable): \_\_\_\_\_      Phone number (include area code): ( )

Street address: \_\_\_\_\_      FAX number (include area code): ( )

City: \_\_\_\_\_      State / Province: \_\_\_\_\_      Country: \_\_\_\_\_      ZIP / Postal Code: \_\_\_\_\_

Contact name:

Contact title:

FDA Document Number:

**Section G Applicant or Sponsor**

Company / Institution name: **SPECTRANETICS CORPORATION** FDA establishment registration number: **1721279**

Division name (if applicable): \_\_\_\_\_ Phone number (include area code): **(719) 633 8333**

Street address: **96 TALAMINE <sup>ms</sup> COURT** FAX number (include area code): **(719) 442 2481**

City: **COLORADO SPRINGS** State / Province: **CO** Country: **USA** ZIP / Postal Code: **80907**

Signature: **Adrian E. Elfe**

Name: **ADRIAN ELFE**

Title: **VP RA/QA**

**Section H Submission correspondent (if different from above)**

Company / Institution name: \_\_\_\_\_  
 Division name (if applicable): \_\_\_\_\_ Phone number (include area code): \_\_\_\_\_

Street address: \_\_\_\_\_ FAX number (include area code): \_\_\_\_\_

City: \_\_\_\_\_ State / Province: \_\_\_\_\_ Country: \_\_\_\_\_ ZIP / Postal Code: \_\_\_\_\_

Contact name: \_\_\_\_\_

Contact title: \_\_\_\_\_

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2006. 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)

(b)(4)

Write the Payment Identification Number on your check.

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

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

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

SPECTRANETICS CORPORATION  
 96 TALAMINE COURT  
 COLORADO SPRINGS, CO 80907

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)  
 840997049

2. CONTACT NAME  
 GUY CHILDS

2.1 E-MAIL ADDRESS  
 guy.childs@spectranetics.com

2.2 TELEPHONE NUMBER (Include Area Code)  
 719-633-8333

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)  
 719-633-4207

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:

- Premarket notification (510(k)); except for third party reviews
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below:

- Original Application

Supplement Types:

- Efficacy (BLA)
- Panel Track (PMA, PMR, PDP)
- Real-Time (PMA, PMR, PDP)
- 180-day (PMA, PMR, PDP)

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

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

NO, I am not a small business

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

(b)(4)

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

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

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

- YES     NO

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

(b)(4)

Form FDA 3601 (08/2003)

**Spectranetics**

96 Talamine Court Colorado Springs, CO 80907  
Phone (719) 633-8333 FAX (719) 633-2248

(b)(4)

(b)(4)

(b)(4)

THIS DOCUMENT HAS A COLORED BACKGROUND AND A SIMULATED WATERMARK ON THE BACK

**Spectranetics**

96 Talamine Court Colorado Springs, CO 80907  
Phone (719) 633-8333 FAX (719) 633-2248

(b)(4)

(b)(4)

**Screening Checklist [510(k)] Submissions Tabulated  
with Section Numbers and Page Numbers**

<b>CHECKLIST ITEM</b>	<b>Section Number</b>	<b>Page Number</b>
Cover Letter	1	1
Table of Contents	2	10
Truthful and Accurate Statement	3	12
Device Trade Name, Classification Name, and Establishment Registration Number	4	13
Device Classification Regulation Number	5	14
Proposed Labeling	6	16
Statement of Indications for Use	7	28
Substantial Equivalence Comparison	8	29
510(k) Summary	9	32
Description of Device	10	36
Identification of Legally Marketed Predicate Device	11	54
Compliance with Performance Standards	12	55
Summary of In Vivo Data	13	57
Class III Certification and Summary	N/A	N/A
Financial Certification or Disclosure	N/A	N/A
510(k) Kit Certification	N/A	N/A
Appendices	14	60

## 2. TABLE OF CONTENTS

### 510(K) SPECTRANETICS 2.5 MM TURBO CATHETER

#### TABLE OF CONTENTS

	<u>Page</u>
1. CDRH Submission Cover Letter	1
CDRH Submission Forms	2
Medical Device User Fee Sheets	6
Screening Checklist [510(k)] Submissions	9
2. Table of Contents - 510(k) Spectranetics CLiRpath System	10
3. Truthful and Accurate Statement, 510(k)	12
4. Device Name / Trade Name / Registration Number	13
5. Device Classification and General Information	14
6. Proposed Labeling	16
A. Package and Labels	16
B. IFU	21
7. Indications for Use Statement	28
8. Substantial Equivalence Comparison	29
A. Identification of & Comparison with Predicate Devices	29
B. Substantial Equivalence Summary and Table	29

## 510(K) SPECTRANETICS 2.5 MM TURBO CATHETER

### TABLE OF CONTENTS (CONTINUED)

	Page
9. 510(k) Summary	32
10. Device Description	36
A. General	36
B. Photographs	41
C. Assembly Drawings	44
D. Bench Testing	49
E. Sterilization, Packaging, Shelf Life, and Biocompatibility	50
11. Identification of Legally Marketed Predicate Device	54
12. Performance Standards [807.87 (d)]	55
13. Summary if <i>In Vivo</i> Data	57
A. Animal Study (Porcine)	57
B. DELTA Study (EU)	58
14. Appendices	60
A. Predicate Device IFU's	61
B. Bench Testing Protocols and Data Reports	68
C. Sterilization and Package Integrity Protocols and Data Reports	130
D. Animal Study – LyChron LLC Protocol 513-1	158

### 3. TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Vice President RA/QA of Spectranetics Corporation, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Neil Burns for AEE  
Signature

Adrian E. Elfe  
Typed name

13 Dec 04  
Dated

(TBD)  
Premarket notification number

4. DEVICE NAME: 2.5 mm Turbo CLiRpath  
Excimer Laser Catheter

510(k): \_\_\_\_\_(TBD)

REGISTRATION NUMBER:

Applicant: Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, Colorado 80907

Registration Number: 1721279

## 5. DEVICE CLASSIFICATION AND GENERAL INFORMATION

<u>Class</u>	Class II
<u>Panel</u>	Cardiovascular
<u>Product Code</u>	MCW
<u>Classification Name</u>	Catheter, Peripheral, Atherectomy. 21 CFR 870.4875

### GENERAL INFORMATION

Spectranetics seeks clearance to market the 2.5 mm Turbo CLiRpath excimer laser catheter for peripheral use (model 225-011). The over-the-wire (OTW) device will be supplied with a tip diameter of 2.5 mm with a working length of approximately 110 cm. The 2.5 mm Turbo catheter model constitutes an addition to the seventeen (17) CLiRpath excimer laser catheter models approved under submission K040067. No change to the already-cleared CLiRpath indication for use is proposed for the Turbo catheter.

Physicians and clinicians will be able to use the 2.5 mm Turbo catheter to access and treat atherosclerotic lesions in the arteries of the legs using either minimally invasive techniques, or surgical access procedures. The Food and Drug Administration (FDA) originally approved Spectranetics brand excimer laser catheters and the CVX 300 excimer laser together as an energy source under PMA 910001 on 19 February 1993, under the trade name CVX 300 Laser Angioplasty System. The CVX 300 Laser Angioplasty System may be described as the combination of a cardiovascular catheter, which contains a bundle of optical fibers and is positioned in contact with an arterial stenosis within a patient's vasculature, with the CVX 300 as a source of ultraviolet laser light energy. The catheter connects to the CVX 300, couples with the beam of 308 nm ultraviolet light produced, and transmits the laser energy to the arterial lesion where the energy assists in ablating and crossing plaque material.

This 510(k) premarket notification seeks clearance to sell a 2.5 mm excimer laser catheter, which can be continuously operated at maximum energy parameters delivering up to 50 millijoules per square millimeter at up to 40 pulses per second (40Hz/50 mJ/mm<sup>2</sup> with "continuous-on" capability). This new model is intended for use exclusively in the lower extremities, and as part of the CVX 300 Laser Angioplasty System.

Spectranetics has completed non-clinical testing: bench testing and an animal study using a porcine model. The non-clinical and bench testing showed the biocompatibility- and mechanical-integrity-related aspects of the new turbo catheter to be equivalent to Spectranetics' CLiRpath catheters, the cited predicate device.

Turbo catheters are designed to achieve maximum luminal gain in the superficial femoral artery through making maximum energy delivery parameters of 40Hz and 50 mJ/mm<sup>2</sup> available to the physician. Also, continuous operation is enabled, instead of a forced 5 to 10 second waiting period between laser pulse trains.

An operator must first advance a guide catheter to the target lesion, so that a guidewire can be also be placed in contact with the lesion. This facilitates the placement of a Turbo catheter in contact with the occlusive tissue. The CVX 300, 308nm laser energy source is then activated

via a footswitch, and ablative photonic energy is transmitted through optical fibers to the Turbo catheter tip. The laser catheter tip, which is in contact with the arterial lesion, directly delivers the laser energy ablating the atherosclerotic occlusive blockage. Ablation assists the mechanical advancement of the catheter, at a rate of no more than 1 mm per second, until the lesion is crossed. Adjunctive therapies may be applied as necessary once the lesion is crossed.

## 6. Proposed Labeling

### A. Package and Labels

Spectranetics excimer laser catheters, including the 2.5 mm Turbo CLiRpath catheter (model 225-011), are packaged using a double-barrier, gas permeable system. This packaging scheme was approved as part of Spectranetics' original PMA 910001, and its amendments. Specifically it consists of sealing a catheter inside a plastic (PETG) tray (#3800-0089) under an adhesive backed Tyvek lid (#3800-0027). This inner sterile barrier is then sealed in a Tyvek pouch (#3800-0025), creating a second sterile barrier. (P910001/S12, approved 24 September 1997). All (100%) catheters are inspected for package integrity after sterilization, and before being placed into outer shelf pack boxes.

Spectranetics applies self-adhesive labels to the sterilization pouch (second sterile barrier) and to the outer box. A paper copy of the applicable Instructions for Use is placed in the outer box with each catheter unit. Copies of the proposed labels for the 2.5 mm Turbo excimer laser catheter (model 225-011) follows this page. Likewise a copy of the package and label assembly drawing is provided.

A copy of the Package Label Assembly drawing for one of the predicate devices (2.5 mm Extreme II catheter, model 225-010), is provided for comparative purposes.

List of Documents attached

Label Pouch, 2.5 Turbo (222-005), 2403-0471  
Label Box, 2.5 Turbo (222-005), 2403-0472  
Package/Label Assembly, 2.5 Turbo, 3650-1219

Package/Label Assembly, 2.5 Extreme II, 3650-1033

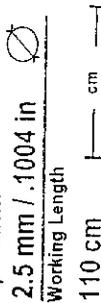
# CLIRpath™

Excimer Laser Catheter

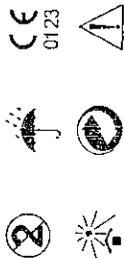
Tip Diameter  
**2.5 mm / .1004 in**

Working Length  
**110 cm**

Max Guidewire  
**0.018 in**



Treefrog Hydrophilic  
 Coating



STERILE EO

Product Number  
 REF **225-011**

Lot Number  
 LOT **1234567**

Use By Date  
**2006-11**

# CLIRpath™

Excimer Laser Catheter

TIP DIAMETER  
 2.5 mm / .1004 in

MAX. GUIDEWIRE  
 0.018 in

WORKING LENGTH  
 110 cm



Specialties

Product Number  
 REF **225-011**

Lot Number  
 LOT **1234567**

Use By Date  
**2006-11**

2.5 mm Tip Diameter  
 110 cm Working Length  
 0.018 in Max Guidewire

OTW

USE BEFORE 2006-11

LOT 1234567

Swedish 2.5 Turbo Extreme II OTW (225-011)

CATALOG NUMBER  
 \*H20422501002\*

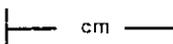
PAGE 10 OF 10

2403-0472-00

# CLiRpath™

Excimer Laser Catheter

## 2.5 Turbo Extreme II OTW

Size	Use with less than or equal to 0.018 inch diameter guidewire	Tip Outer Diameter	2.5mm / .1004" 
Length	110 cm 	Use By Date	 2006-11
Product Number	REF 225-011	Lot Number	LOT 1234567

Energy Range for catheters calibrated at ~~50~~ <sup>45</sup> mJ/mm<sup>2</sup> (mJ) ~~84 - 86~~ <sup>75.5 - 77.5</sup>

STERILE AND NON-PYROGENIC in unopened, undamaged package. This device is intended for ONE ( 1 ) use only. DO NOT resterilize. Read all instructions prior to use. Store in a cool dry place.

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

CONTENTS : 1 Unit.

\*\*\*M20422501001.\* CATALOG NUMBER  
Spectranetics 2.5mm Turbo Extreme II OTW 225-011

\*\*\*\$11061234567.K\*  
USE BEFORE  2006-11 LOT 1234567

\*\*\*M20422501001.\* CATALOG NUMBER  
Spectranetics 2.5mm Turbo Extreme II OTW 225-011

\*\*\*\$11061234567.K\*  
USE BEFORE  2006-11 LOT 1234567

\*\*\*M20422501001.\* CATALOG NUMBER  
Spectranetics 2.5mm Turbo Extreme II OTW 225-011

\*\*\*\$11061234567.K\*  
USE BEFORE  2006-11 LOT 1234567

\*\*\*M20422501001.\* CATALOG NUMBER  
Spectranetics 2.5mm Turbo Extreme II OTW 225-011

\*\*\*\$11061234567.K\*  
USE BEFORE  2006-11 LOT 1234567

\*\*\*M20422501001.\* CATALOG NUMBER  
Spectranetics 2.5mm Turbo Extreme II OTW 225-011

\*\*\*\$11061234567.K\*  
USE BEFORE  2006-11 LOT 1234567



STERILE EO  
NICHT PYROGEN  
NO PIROGENO  
NON PIROGENO  
NON PYROGENE  
INTE - PYROGEN

CE  
0123



Manufactured by: **Spectranetics**

96 Talamine Court, Colorado Springs, Colorado 80907 USA  
1-800-231-0978, Tele: 719-633-8233, Fax: 719-633-7248  
European Office:  
Plesmanstraat 6, 3833 LA Leusden, The Netherlands  
Tele: +31 33 434 7050, Fax: +31 33 434 7051  
www.spectranetics.com

2403-0471-0





## **B. Proposed IFU**

A copy of the proposed Instructions for Use of the 2.5 mm Turbo catheter, document 7030-0153, follows.

## CLiRpath™ Excimer Laser Catheters

Cool Laser Revascularization for Peripheral Artery Therapy  
Extreme® (OTW) and Vitesse® (RX) Catheter Models

### Instructions For Use

#### Table of Contents

1. DESCRIPTION	1
2. INDICATIONS FOR USE	2
3. CONTRAINDICATIONS	2
4. WARNINGS	2
5. PRECAUTIONS	2
6. POTENTIAL ADVERSE EVENTS	2
7. CLINICAL STUDIES	3
8. INDIVIDUALIZATION OF TREATMENT	3
9. OPERATOR'S MANUAL	4
10. HOW SUPPLIED	4
10.1 STERILIZATION	4
10.2 INSPECTION PRIOR TO USE	4
10.3 PROCEDURE SET UP	4
10.4 COMPATIBILITY	4
11. DIRECTIONS FOR USE	4
12. COMPANY INFORMATION	6

For Extreme®, over the wire (OTW) catheters, a Luer adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the appropriate sized guidewire (0.014", 0.016", 0.018", 0.025", and 0.035") see inset below.

For Vitesse®, rapid exchange (RX) catheters, the guidewire lumen is formed only through the last 9 cm of the distal tip, which has direct patient contact, and is concentric with the fiber array; see inset below.

For Vitesse®-E, rapid exchange (RX) eccentric catheters, the laser catheter consists of eccentrically aligned optical fibers and a stainless steel torque device encased within a polyester shaft. There are two major portions of the laser catheter shaft, the proximal portion which terminates at the laser connector, and the distal portion which terminates at the tip having direct patient contact. The torque device extends from the torque handle, located at the y-adapter, through the entire 140 cm of the distal portion of the catheter, and terminates in the distal tip. There is a mechanism within the torque handle which limits the turns to five full rotations in each direction. The torque handle also has an indicator displaying its range of motion. The laser catheter is packaged with the indicator in the center of its range (see inset below). The torque response is 6:1; six turns of the torque handle result in one 360° turn of the distal tip. A radiopaque marker band with radiolucent window is located on the distal tip of the laser catheter to aid

#### 1. Description

Spectranetics CLiRpath™ excimer laser catheters are percutaneous intravascular devices constructed of multiple optical fibers arranged around a guidewire lumen.

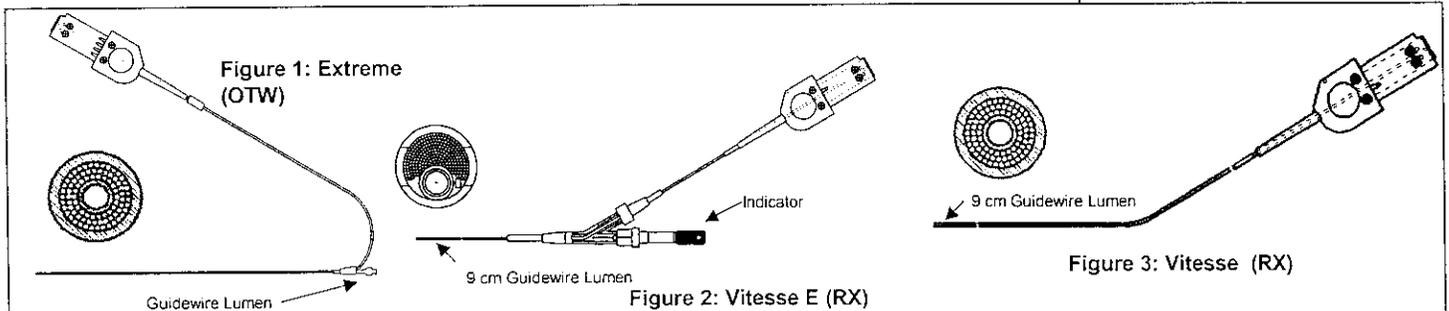


Table 1.1 CLiRpath Excimer Laser Catheter Models

Device OD Outer Diameter (mm)	Model Number	Max. Guidewire Lumen (in.)	Max. Tip Outside Diameter (in.)	Min. Tip Inside Diameter (in.)	Max. Shaft Diameter (in.)	Min Tail Tube Length (cm)	Min Working Length (cm)
<i>Extreme (OTW) Catheter Specifications</i>							
0.9 mm	110-001	0.014	0.038	0.0155	0.047	183	130
0.9 mm X80	110-002	0.014	0.038	0.0155	0.047	183	130
1.4 mm	114-001	0.014	0.056	0.017	0.056	183	131
1.7 mm	117-002	0.018	0.064	0.021	0.065	183	131
2.0 mm	120-001	0.018	0.077	0.021	0.076	183	131
2.0 mm II	220-006	0.018	0.0775	0.026	0.083	168	131
2.2 mm	222-005	0.035	0.088	0.037	0.089	168	120
2.3 mm II	223-001	0.035	0.092	0.039	0.094	168	120
2.5 mm	225-004	0.035	0.1	0.037	0.098	168	100
2.5 mm II	225-010	0.035	0.099	0.039	0.101	168	100
2.5 mm Turbo	225-011	0.18	0.1004	0.025	0.102	168	110
Device OD Outer Diameter (mm)	Model Number	Max. Guidewire Lumen (in.)	Max. Tip Outside Diameter (in.)	Min. Tip Inside Diameter (in.)	Max. Shaft Diameter (in.)	Min Tail Tube Length (cm)	Min Working Length (cm)
<i>Vitesse (RX) Catheter Specifications</i>							
0.9 mm	110-003	0.014	0.038	0.0155	0.049	183	131
0.9 mm X80	110-004	0.014	0.038	0.0155	0.049	183	131
1.4 mm	114-009	0.014	0.057	0.0175	0.062	183	131
1.7 mm	117-016	0.014	0.0685	0.0175	0.072	183	131
1.7 mm E	117-205	0.014	0.0665	0.0175	0.072	183	129
2.0 mm E	120-008	0.018	0.0785	0.0205	0.084	183	129
2.0 mm	120-009	0.014	0.08	0.0175	0.084	183	131

localization within the coronary vasculature in conjunction with fluoroscopy.

### Mechanism of Action for CLiRpath Catheters

The multifiber laser catheters transmit ultraviolet energy from the Spectranetics CVX-300<sup>®</sup> to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photo-ablate fibrous, calcific, and atheromatous lesions, thus recanalizing diseased vessels (photo ablation is the process by which energy photons cause molecular bond disruption at the cellular level without thermal damage to surrounding tissue). The Spectranetics laser catheters have a proprietary lubricious coating to ease their trackability through arteries.

### Glossary of Special Terms

*Retrograde Fashion* = In the direction opposite to blood flow.

*Antegrade Fashion* = In the direction of blood flow.

*Baseline Angiography* = Angiographic record of blood vessels.

*Contralateral Approach* = Arterial access by a crossover approach.

## 2. Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Note: Successful step-by-step passage of guide wires does not necessarily ensure relief of critical limb ischemia. Additional procedures may be required.

## 3. Contraindications

- No known contraindications.

## 4. Warnings

**Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.**

Spectranetics Excimer Laser Catheters require CVX-300<sup>®</sup> software versions 3.708 or 3.808 and higher.

When the laser catheter is in the body, it should be manipulated only while it is under fluoroscopic observation with radiographic equipment that provides high quality images.

The use of the CVX-300<sup>®</sup> Excimer Laser System is restricted to physicians who are trained in peripheral vascular intervention and who meet the training requirements listed below. These requirements include, but are not limited to:

1. Training of laser safety and physics.
2. Review of patient films of lesions that meet the indications for use.
3. A review of cases demonstrating the CLiRpath technique in occlusions that meet the indications for use.
4. A review of laser operation followed by a demonstration of the CVX-300<sup>®</sup> Excimer Laser System.

5. Hands on training with the CVX-300<sup>®</sup> Excimer Laser System and appropriate model.
6. A fully trained Spectranetics representative will be present to assist for a minimum of the first three cases.
7. Following the formal training session, Spectranetics will make available additional training if so requested by the physician, support personnel, the institution or Spectranetics.

## 5. Precautions

This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for **SINGLE USE ONLY** and must not be resterilized and/or reused.

Store in a cool, dry place. Protect from direct sunlight and high temperatures (*greater than 60°C or 140°F*).

The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised. Do not use catheter product if its "Use Before Date," found on package labeling, has been passed.

Before use, examine carefully all of the equipment to be used in the procedure for defects. Do not use any equipment if it is damaged.

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially biohazardous materials.

Read the Operator's Manual (7030-0035 or 7030-0068) thoroughly before operating the Excimer Laser System. Pay particular attention to the Warnings and Responsibility section of the manual which explains Notes, Cautions, and Warnings to be followed to ensure safe operation of the CVX-300<sup>®</sup>.

During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution's PTA protocol.

## 6. Adverse Events

Use of the Spectranetics CVX-300<sup>®</sup> Excimer Laser System may contribute to the following complications:

Events Observed during CLiRpath Clinical Studies (see Section 7)

Procedural Complications	Serious Adverse Events
<ul style="list-style-type: none"><li>• Spasm</li><li>• Major dissection</li><li>• Thrombus</li><li>• Distal embolization</li><li>• Perforation</li><li>• Other</li></ul>	<ul style="list-style-type: none"><li>• Death</li><li>• Reintervention</li><li>• ALI</li><li>• Major amputation</li><li>• Bypass Surgery</li><li>• Hematoma with Surgery</li></ul>

In-Hospital Complications

- Reocclusion
- Pseudoaneurysm
- Renal failure
- Bleeding

Potential Averse Events NOT Observed during CLiRpath Clinical Studies (see Section 7)

- Nerve Injury
- AV Fistula Formation
- Endarterectomy
- Infection
- Stroke
- Myocardial Infarction
- Arrhythmia

No long term adverse effects on the arterial vessel wall, due to peripheral excimer laser recanalization, are known at this time.

## 7. Clinical Studies

Data presented in this IFU comprise of a subset of patients pooled from three sources of consecutively treated patients presenting with Critical Limb Ischemia (CLI), who were poor surgical candidates:

- LACI Phase 2 – a subset of patients from a prospective IDE registry conducted in 2001-2002 at 14 sites in the US and Germany. The subset includes 26 limbs (in 25 patients) treated at 7 sites from the US and Germany in which the step by step CLiRpath laser recanalization technique was utilized. In 13 of these cases, step-by-step technique was utilized *ab initio*, that is, without first attempting to cross the occlusion with a guidewire.
- LACI Belgium - a subset of a 51-patient prospective registry conducted at 6 sites in Belgium. The subset includes 9 limbs (in 9 patients) treated at 3 sites in Belgium in which the step by step CLiRpath laser recanalization technique was utilized.
- Louisiana case series – a subset drawn from 62 cases included in an on-going data compilation by a single physician group in central Louisiana, the Cardiovascular Institute of the South (CIS). This subset of patients consists of 12 limbs (in 12 patients) in which the step by step CLiRpath laser recanalization technique was utilized.

Table 7.1 Procedure Information

Locations of vascular lesions (n=205)	
SFA	138 (67%)
Popliteal	23 (11%)
Infrapopliteal	42 (20%)

Angiographic Results (n=47 limbs)	
Lesions per limb	4.4
Average lesion length	73.4 ± 7.3 (mm)
Straight line flow to foot established	37 (79%)
Stent implanted	28 (60%)
Crossing Success Overall*	37 (79%)
Crossing Success after Guidewire Attempt	24/34 (71%)
Crossing Success ab initio Cases	13/13 (100%)
Procedure success**	34 (72%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

\*Crossing Success data has been stratified for step-by-step cases after conventional guidewire attempts in 24 limbs, and ab initio in 13 limbs.

\*\*Procedure success: ≤50% final residual stenosis

Table 7.2 Complications, n=47 limbs

Procedural Complications	
Spasm	1 (2%)
Major dissection	4 (9%)
Thrombus	1 (2%)
Distal embolization	3 (6%)
Perforation	3 (6%)
Other	5 (11%)
In-Hospital Complications	
Reocclusion	1 (2%)
Pseudoaneurysm	1 (2%)
Renal failure	1 (2%)
Bleeding	1 (2%)
Infection	0 (0%)
Other	0 (0%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

Table 7.3 Cumulative Serious Adverse Events (SAEs) through 6-month follow-up, for n=47 limbs

Death	3 (6%)
MI or Stroke	0 (0%)
Reintervention	6 (13%)
ALI	1 (2%)
Major amputation	2 (4%)
Bypass Surgery	2 (4%)
Endarterectomy	0 (0%)
Hematoma with Surgery	2 (4%)
Total	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

MI = Myocardial Infarction. ALI = Acute Limb Ischemia.

Table 7.4 Outcomes by Intention-to-Treat Analysis, n=47

Crossing Success	37 (79%)
Procedure Success	34 (72%)
Limb Salvage	40 (85%)
Death, any cause	3 (6%)
Any SAE	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

## 8. Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the CLiRpath device.

Use of CLiRpath devices may be considered after initial conventional crossing attempts with guidewires are unsuccessful due to:

- A rounded or eccentric occlusion stump deflecting the guidewire to a subintimal passage.
- The guidewire repeatedly being deflected into a large collateral branch flush with the occlusion stump.
- Calcification obstructing completion of guidewire passage within the obstructed lumen.

Additionally, recanalization of native arteries may be considered in patients presenting with occluded bypass grafts.

Patient selection and clinical techniques should be conducted according to instructions provided in Section 2, "Indications for Use," and Section 9, "Operator's Manual."

## 9. Operator's Manual

The devices described in this document can be operated within the following energy ranges on the CVX-300®:

Table 9.1 Energy Parameters

Device O.D.	Model No.	Fluence	Repetition Rate	Laser On/Off Time
<b>Extreme (OTW) Catheters</b>				
0.9 mm	110-001	30-60	25-40	5 sec on/10 sec off
0.9 mm X/80	110-002	30-80	25-80	10 sec on/5 sec off
1.4 mm	114-001	30-60	25-40	5 sec on/10 sec off
1.7 mm	117-002	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-001	30-60	25-40	5 sec on/10 sec off
2.0 mm	220-006	30-60	25-40	10 sec on/5 sec off
2.2 mm	222-005	30-60	25-40	5 sec on/10 sec off
2.3 mm	223-001	30-60	25-40	10 sec on/5 sec off
2.5 mm	225-004	30-50	25-40	5 sec on/10 sec off
2.5 mm	225-010	30-50	25-40	10 sec on/5 sec off
2.5 mm	225-011	See note 1	25-40	Continuous On
<b>Vitesse (RX) Catheters</b>				
0.9 mm	110-003	30-60	25-40	5 sec on/10 sec off
0.9 mm X/80	110-004	30-80	25-80	10 sec on/5 sec off
1.4 mm	114-009	30-60	25-40	5 sec on/10 sec off
1.7 mm	117-016	30-60	25-40	5 sec on/10 sec off
1.7 mm E	117-205	30-60	25-40	5 sec on/10 sec off
2.0 mm E	120-008	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-009	30-60	25-40	5 sec on/10 sec off

Recommended calibration settings: 45 Fluence, 25 Hz.

**Note 1:** max fluence listed on box label.

## 10. How Supplied

### 10.1 Sterilization

**For single use only.** Do not re-sterilize and/or reuse.

The Spectranetics laser catheters are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

### 10.2 Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken. All equipment to be used for the procedure, including the catheter, should be examined carefully for defects. Examine the laser catheter for bends, kinks or other damage. Do not use if it is damaged.

### 10.3 Procedure Set Up

Some or all of the following additional materials, which are not included in the laser catheter package, may be required for the procedure (these are single use items only—do not resterilize or reuse):

- Introducer sheaths and/or femoral guiding catheter(s) in the appropriate size and configuration to select the peripheral artery and facilitate largest laser catheter to be used.
- Tuohy-Borst "y" adapter or hemostatic valve(s).
- Sterile normal saline or Lactated Ringer's solution
- Standard contrast media
- 0.014", 0.016", 0.018", 0.025", or 0.035" guidewires

### 10.4 Compatibility

The Spectranetics' excimer laser catheter is designed and intended to be used exclusively with the Spectranetics CVX-300® Laser System.

Do not use in combination with any other laser system.

## Guidewire Compatibility

See Catheter Specification Table in Section 1.

## 11. Directions for Use

Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the laser catheter from the tray while supporting the black laser connector, also known as the proximal end, proximal coupler, or proximal connector. Please note that the proximal end of the laser catheter connects only to the CVX-300®, and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the CVX-300® and position the laser catheter in the laser system extension pole. Calibrate the laser catheter following the instructions provided in the CVX-300® Operator's Manual (7030-0035 or 7030-0068).

1. Use standard femoral puncture technique to insert a 5 Fr. to 9 Fr. (depending on the largest interventional device to be used during treatment) introducer sheath into the common femoral artery in antegrade or retrograde fashion for contralateral approaches. Heparinize intravenously using the PTA protocol for heparinization.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014", 0.016", 0.018", 0.025", or 0.035" guidewire to the peripheral occlusion via the introducer sheath or guiding catheter.
4. Size and choose the laser catheter appropriately:

Table 11.1 Recommended Sizing

Catheter Size	Proximal Vessel Diameter
0.9 mm	≥1.5 mm
0.9 mm X/80	≥2.0 mm
1.4 mm	≥2.2 mm
1.7 mm	≥2.5 mm
2.0 mm	≥3.0 mm
2.2 mm	≥3.2 mm
2.3 mm	≥3.2 mm
2.5 mm	≥3.5 mm

Note: Choosing an eccentric laser catheter may be appropriate when lesion morphology or the location and tortuosity of the occluded vessel imply eccentric ablation would assist in following the true vessel lumen. Eccentric ablation may help avoid subintimal passage in such cases.

5. *This step applies only to Extreme catheter models.* Inject 5-10cc of heparinized saline or Lactated Ringer's solution through the laser catheter to flush the guidewire lumen. Attach a rotating hemostatic valve to the guidewire port into the guidewire lumen (See Figure 4). Introduce the distal tip of the Spectranetics laser catheter over the selected guidewire. Under fluoroscopic control, guide the laser catheter to the lesion. The laser catheter's radiopaque band marker indicates its position relative to the lesion.

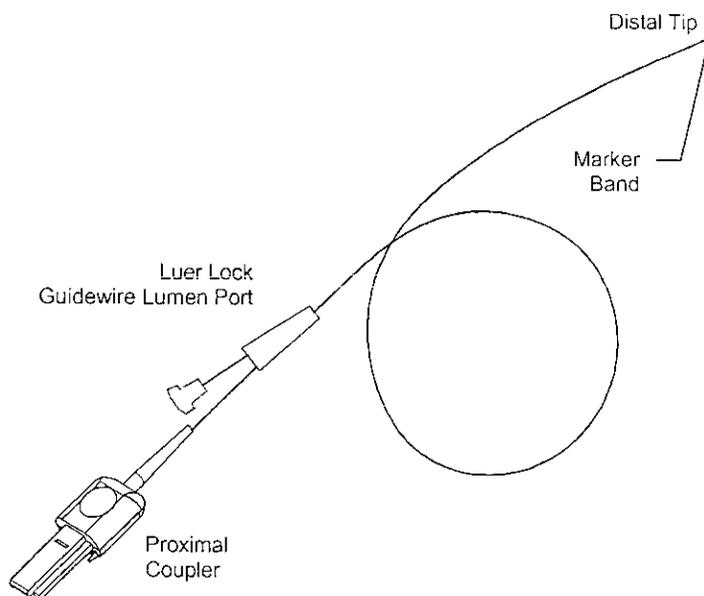


Figure 4 (not to scale)

6. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
7. Following confirmation of the laser catheter's position in contact with the target lesion and using normal saline or Lactated Ringer's solution:
  - a. Flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors,
  - b. Flush all residual contrast media from the lasing site and vascular structures adjacent to the lasing site, prior to activating the CVX-300® laser system.
  - c. Please refer to the Saline Infusion Protocol section of these Instructions for Use and perform saline flush and infusion per the instructions.
8. Depress the footswitch, activating the CVX-300®, and **slowly**, less than 1 mm per second, advance the laser catheter 2–3 mm into the total occlusion, allowing the laser energy to remove the desired material. Release the footswitch to deactivate the CVX-300®.

**Note**  
Advancing the laser catheter through moderately calcified lesions may require more pulses of laser energy than fibrous atherosclerotic tissue.

9. Advance the guidewire beyond the distal tip of the laser catheter further into the occlusion, a few millimeters, and reactivate the laser as described in Step 8 above.
10. Continue in this step-by-step manner where the guidewire and then the laser catheter are advanced and activated (mm by mm) until the catheter reaches the last 3-5 mm of the occlusion.

11. Cross the last 3-5 mm of the occlusion and enter the patent distal vessel with the guidewire first, followed by the activated laser catheter over the wire.
12. Leaving the guidewire in position, pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.
13. Additional laser passes may be performed over the wire to achieve greater debulking of the lesion.

**Note**  
If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter outer surface, inner lumen, and tip with heparinized saline to prevent blood from sticking. Blood remaining on the laser catheter may diminish the efficiency of the laser catheter.

If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the CVX-300®. The fluence and repetition rates can be increased in order to advance. To avoid the potential of heat build-up, the catheter must be advanced while lasing.

14. There is no need to remove the laser catheter from the patient in order to increase or decrease either the fluence or pulse repetition rate; as the laser catheter was previously calibrated. Refer to the CVX-300® Excimer Laser System Operator's Manual, 7030-0035 or 7030-0068.

**Caution**  
All patients should be monitored for blood pressure and heart rate during the procedure.

15. Following laser recanalization, perform follow up angiography and balloon angioplasty if needed. Stenting may be performed as required, in instances of acute recoil, major perforation, etc.
16. Recommended pharmacology follow up to be prescribed by the physician.

**EXCIMER LASER SALINE INFUSION PROTOCOL**

**Note**  
This technique requires two operators. It is recommended that the primary physician operator advance the laser catheter and operate the laser system foot pedal. A scrub assistant should manage the saline infusion control syringe and (if appropriate) depress the fluoroscopy pedal.

- A. Before the laser procedure, warm a 500cc bag of 0.9% normal saline (NaCl), or Lactated Ringer's (LR) solution, to 37°C. It is not necessary to add heparin or potassium to the saline/LR solution. Connect the bag of warmed saline/LR to a sterile intravenous line and terminate the line at a port on a triple manifold.

- B. if applicable, cannulate the ostium of the artery with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter **not** have side holes.
- C. Under fluoroscopic guidance, advance the laser catheter into contact with the lesion. If necessary, inject contrast to help position the tip of the laser catheter. If contrast appears to have become entrapped between the *laser* catheter tip and the lesion, the *laser* catheter may be retracted slightly (1-2mm) to allow antegrade flow and contrast removal while flushing the system with saline/LR. **However, before lasing, ensure that the laser catheter tip is in contact with the lesion.**
- D. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline/LR through the manifold into the control syringe.
- E. Remove the original control syringe from the manifold and replace it with a fresh 20cc luer-lock control syringe. This new 20cc control syringe should be primed with saline/LR prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20cc control syringes.)
- F. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and introducer sheath or guide catheter, with at least 20-30cc of saline/LR (several syringes of saline/LR). When this initial flushing is completed, refill the 20cc control syringe with saline/LR.
- G. Under fluoroscopy, confirm that the tip of the laser catheter is in contact with the lesion (advance the laser catheter if necessary), but do **not** inject contrast.
- H. When the primary operator indicates that he/she is ready to activate the laser system, the scrub assistant should turn the manifold stopcock off to pressure and inject 10cc of saline/LR as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
- I. After the injection of the initial 10cc bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3cc/second. This portion of the saline/LR infusion is to displace and/or dilute the antegrade blood flow entering the laser ablation field. **At the instant the scrub assistant slows down the injection rate, the primary operator should activate the laser system by depressing the foot pedal and begin a lasing sequence.**
- J. The lasing sequence (train) should last for 2 -10 seconds (maximum of 10 seconds).
- K. Terminate the saline/LR injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20cc of saline/LR in preparation for the next lasing sequence.
- L. Each subsequent laser train should be preceded by a bolus of saline/LR and performed with continuous saline/LR infusion as described in steps H-K.
- M. If contrast is used to assess treatment results during the course of a laser treatment, repeat steps D - G **prior** to reactivation of the laser system (before activating the laser as described in steps H - K).

**Note**

Depending on which approach is used, antegrade or contralateral, saline/LR can be administered through the sheath (antegrade approach) or laser catheter inner lumen (contralateral approach). When the contralateral approach is used, smaller diameter guidewires are suggested to allow adequate saline/LR infusion at the treatment site.

**12. Company Information**

The company's standard one-year product warranty and remedy are exclusive and expressly in lieu of all other warranties expressed or implied either in fact or by operation of law, statutory or otherwise, including warranties of merchant ability and fitness for use or for any particular purpose and of all other liabilities or obligations on the part of the company relating in any way to the CVX-300<sup>®</sup> Excimer Laser System, whether arising from personal injury, property damage or otherwise. The company neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System. Notwithstanding the generality of the foregoing, (a) the company shall have no liability whatsoever for special, consequential, incidental or punitive damages of any kind arising out of the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System, and (b) the company's liability shall in no event exceed the original purchase price of the CVX-300<sup>®</sup> Excimer Laser System.

**Spectranetics<sup>®</sup>**

Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, Colorado 80907-5186  
USA  
Telephone 719-633-8333

Spectranetics International BV  
Plesmanstraat 6  
3833 LA Leusden  
The Netherlands  
Telephone 31-33-434-7050

## 7. Statement of Indication for Use

**Device Name: Spectranetics 2.5 mm Turbo™  
Excimer Laser Catheter**

### Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Prescription Use **XXXX**  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

## 8. Substantial Equivalence Comparison

### A. Identification of & Comparison with Predicate Devices

The Spectranetics 2.5 mm Turbo laser catheter (model 225-011) for atherectomy in peripheral arteries is substantially similar in form, fit, and function to Spectranetics' CLiRpath laser catheters (K040067). Please refer to the table of device characteristics to follow.

*Form:* Spectranetics' 2.5 mm Turbo laser catheter for peripheral use is equivalent to the CLiRpath predicate devices in form. All of these catheters, the 2.5 mm Turbo and the previously approved CLiRpath predicate devices, consist of long tubes containing optical fibers which transmit energy to the device tip. The proximal ends of each device couple to the Spectranetics CVX 300 excimer laser, which produces 308 nm laser light for transmission to arterial lesions. The distal portions of each device penetrate a patient's peripheral arterial tree at a puncture site, are considered minimally invasive, and consist of biocompatible materials. Finally, each of the devices uses (b) (4) to permit radiographic visualization of the catheter location during clinical procedures.

*Fit:* 2.5 mm Turbo laser catheters for peripheral use are equivalent to other CLiRpath catheters in fit. The tip diameter is the same 2.5 mm as that for the 2.5 mm Extreme and Extreme II models of CLiRpath catheters. The patient contact length for the 2.5 mm Turbo catheter (110 cm) is within the range for the CLiRpath predicate product line (95 to 135 cm). This catheter length permits access to the lower extremities from a puncture site, while allowing control of the catheter via external manipulations.

*Function:* Substantial equivalence exists between the function of the 2.5 mm Turbo CLiRpath laser catheter and previously approved Spectranetics CLiRpath laser catheters. Once in contact with atherosclerotic material each of these devices is activated to disrupt and cross the lesion. All Spectranetics laser catheters ablate occlusive material using excimer laser energy – coherent laser light at 308 nm. Ablated material is removed via the patient's reticuloendothelial system when Spectranetics laser catheters are used, regardless of model. The number of optical fibers built into the 2.5 mm Turbo laser catheter has been increased to 128, from a count of only 96 for the 2.5 mm Extreme II laser catheter predicate. However, the maximum operational energy setting remains the same as that for the 2.5 mm Extreme II model (50 mJ/mm<sup>2</sup> at 40 pulses per second [40 Hz]). Coupling efficiency with the CVX 300 excimer laser source therefore improves due to the increased number of light transmitting fibers in the 2.5 mm Turbo catheter, without changing the energy density delivered to the patient. In all cases, CLiRpath catheters disrupt occlusive material while opening a channel through the treated artery, and the 2.5 mm Turbo laser catheter remains functionally equivalent in this regard.

Please find the IFU copy for the predicate CLiRpath devices in Section 14, Part A. It should be emphasized that the Intended Use statement for the 2.5 Turbo CLiRpath catheter is identical to that for all other CLiRpath predicate catheters.

Please refer to Table 8-B, in Section 8B, for a tabulation of device characteristics.

## **B. Substantial Equivalence Summary and Table**

The Spectranetics 2.5 mm Turbo laser catheter for peripheral use is equivalent in form, fit, and function to any of seventeen (17) predicate devices manufactured using the Spectranetics trade name, "CLiRpath." CLiRpath excimer laser catheters received market clearance under section 510(k) under number K040067, in April 2004.

CLiRpath catheters consist of a piece of tubing with a working length of approximately 100 cm, and a diameter between 0.9 mm and 2.5 mm. The catheters communicate laser energy (308nm) to an occlusion within a patient's arteries in the lower limbs. Communicated laser energy disrupts occlusive material in contact with the laser catheter tip, ablating the blockage and permitting its removal via the patient's endoreticular system. The pathway opened by the 2.5 mm Turbo catheter both establishes blood flow through the vessel and may facilitate subsequent placement of other devices and interventions. Therefore, any differences in size ranges, materials, flexibility, or technological characteristics (including energy ranges) are considered functionally equivalent in that they allow physicians an appropriate choice of models for treating various types of peripheral artery disease.

The Device Characteristics table on the following page summarizes the specific aspects of form, fit, and function for the Spectranetics 2.5 Turbo laser catheter vs. the CLiRpath predicate.

Continued next page

Device Characteristics Table 8-B: 2.5 mm Turbo CLiRpath Excimer Laser Catheter to Spectranetics CLiRpath Laser Catheters

	Spectranetics 2.5 mm Turbo Excimer Laser Catheter	Spectranetics CLiRpath Laser Catheters
Intended Use Summary	For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.	For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.
Tip Diameter	2.5 mm (0.100")	0.9 mm to 2.5 mm (0.035" to 0.099")
Working Length (Patient Contact)	110-115 cm	100-135 cm
Materials of Construction	(b) (4)	
Design		
Technical Features		
Operating Principles	Transmits 308 nm ultraviolet light to catheter tip, assisting catheter advancement by <u>ablating plaque refractory to penetration.</u>	Transmits 308 nm ultraviolet light to catheter tip, assisting catheter advancement by <u>ablating plaque refractory to penetration.</u>
Accessories & Interface with other Devices	Exclusively for use with Spectranetics CVX 300 excimer laser system. Requires use of standard accessory devices.	Exclusively for use with Spectranetics CVX 300 excimer laser system. Requires use of standard accessory devices.

## 9. 510(k) Summary

Please refer to the 510(k) Summary on the following three (3) pages.

## 510(k) SUMMARY

### SUBMITTER INFORMATION

- A. Company Name: Spectranetics Corporation, Inc.
- B. Company Address: 96 Talamine Court  
Colorado Springs, Colorado 80907
- C. Company Phone: 719-633-8333 / 1-800-633-0960
- D. Company Facsimile: 719 442 2248
- E. Contact Person: Adrian Elfe  
Vice President  
Quality Assurance & Regulatory Affairs Compliance

### DEVICE IDENTIFICATION

- A. Device Trade Name: 2.5 mm Turbo CLiRpath Excimer Laser Catheter
- B. Device Common Name: Laser Catheter
- C. Classification Name: Catheter, Peripheral, Atherectomy
- D. Device Class: Class II (per 21 CFR 870.4875)
- E. Device Code: MCW

### IDENTIFICATION OF PREDICATE DEVICES

Spectranetics CLiRpath excimer laser catheters for peripheral use, cleared to market under 510(k) K040067, serve as predicate to the 2.5 mm Turbo CLiRpath Excimer Laser Catheter.

## **DEVICE DESCRIPTION**

Spectranetics' laser atherectomy catheters, including the 2.5 mm Turbo CLiRpath catheter for peripheral use, consist of a bundle of optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from a source to the tip of the catheter. The catheter is inserted into a patient's vasculature along the length of a previously inserted medical guidewire, allowing the attending physician to deliver laser energy targeted to a lesion (blockage) in the blood vessel. The 2.5 mm Turbo catheter is designed for "over-the-wire" interventional techniques. Laser energy impinged on a blockage ablates, or debulks, the lesion material re-establishing blood flow within the vessel, and permitting placement of devices used in vascular interventions.

The Spectranetics Turbo laser catheter is supplied with a tip diameter of 2.5 mm, appropriate for interventional use in the peripheral vasculature of the leg.

## **INTENDED USE**

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

## **COMPARISON TO PREDICATE DEVICES**

The Spectranetics 2.5 mm Turbo Excimer Laser Catheter for peripheral use is substantially equivalent in form, fit, and function to other Spectranetics CLiRpath laser catheters, which received market clearance under section 510(k) rules. The 2.5 mm Turbo catheter is an addition to the CLiRpath line of catheters, with the following enhancements.

- Increased lubricity
- Improved efficiency in energy delivery of 308 nm laser light
- Continuous "on" capability

The 2.5 mm Turbo laser catheter consists of a piece of tubing with a working length of approximately 110 cm, and a diameter of 2.5 mm. The catheters communicate excimer laser energy at 308 nm to an occlusion within a patient's targeted peripheral artery. Communicated energy disrupts occlusive material, such as arterial plaque, and permits its removal via the patient's endoreticular system. The pathway opened by either the predicate device or the Turbo catheter, facilitates subsequent placement of other devices and interventions, and re-establishes blood flow within the diseased vessel.

## **BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING**

Biocompatibility of both component materials and the finished 2.5 mm Turbo catheter have been confirmed in accord with the ISO 10993 series of standards, Biological Evaluation of Medical Devices. Spectranetics conducts and maintains valid ethylene oxide sterilization processes in accord with ISO 11135, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. Package integrity is initially validated, and, in addition, visually verified for 100% of Spectranetics devices prior to transfer to finished goods inventory.

Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. All CLiRpath excimer laser catheter models meet or exceed both Spectranetics in-house requirements, and requirements listed in ISO 10555-1, Sterile, Single-use Intravascular Catheters – Part 1: General Requirements.

## **NON-CLINICAL STUDIES**

Spectranetics confirmed safety and equivalent efficacy in the peripheral anatomy for the 2.5 mm Turbo laser catheter using a porcine model, in accord with a protocol compliant with good laboratory practices (GLP's). No complications were noted during treatment of the iliac and femoral arteries in the animal model. Histological evaluation of harvested arterial segments showed no deleterious tissue damage after exposure to the 2.5 mm Turbo catheter operating at maximum energy parameters. Comparisons to treatment with CLiRpath laser catheters, the cited predicate device, indicated that the 2.5 mm Turbo catheter was equivalent with respect to both safety and functionality.

## **CONCLUSION**

A GLP-compliant study using a porcine model verified the safety and performance characteristics for the Spectranetics 2.5 mm Turbo laser catheter when deployed for use in the treatment of peripheral arterial disease. In vitro laboratory tests, as well as qualification and validation studies, have confirmed that 2.5 mm Turbo catheters meet manufacturing and design specifications. All of these data combined establish substantial equivalence to the CLiRpath predicate device.

## 10. Device Description

### A. General

1. Configuration and Model Listing: All Spectranetics brand laser atherectomy catheters consist of a bundle of optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from the Spectranetics CVX 300 Excimer Laser to the tip of the catheter. After removing the catheter from its packaging, the user inserts an optical connector on the proximal end of the catheter into a mating receptacle on the laser. The other end of the catheter is fed into a patient's vasculature along the length of a previously inserted medical guidewire, allowing the attending physician to deliver laser energy targeted to a lesion (blockage) in the blood vessel. The 2.5 mm Turbo catheter is an over-the-wire catheter model, with a guidewire lumen extending through the entire distal portion of the interventional device. Laser energy impinging on a blockage ablates, or debulks, the lesion material thus opening the vessel, permitting subsequent placement of devices used in vascular interventions.

The 2.5 mm Turbo laser catheter may be used to cross lesions using the step by step technique, when deemed necessary by the attending physician. This technique does not require the guidewire to completely cross a target lesion prior to catheter advancement. The guidewire is advanced to the target lesion and is then used to facilitate the placement of the laser catheter tip against the lesion. The laser energy is activated allowing the catheter to advance a few millimeters. The guidewire is then advanced a few millimeters beyond the catheter tip, to probe for a path through the remaining occlusion length. If no such path can be found, the laser catheter is advanced to the end of the guidewire, and the laser is activated again. These steps are repeated until the laser catheter and guidewire cross the lesion. Spectranetics terms this step-by-step process the CLiRpath technique; the 2.5 mm Turbo catheter is included in the CLiRpath product line.

Spectranetics intends to market a single model (225-011) of the Turbo catheter with a tip diameter of 2.5 mm. Model 225-011 is "pin-coded" to function properly only with the Spectranetics CVX 300® excimer laser. The user can adjust the operational energy settings within the limits cited in Table 10.A1, below.

Table 10A1: Energy Parameter Settings – Ranges for 2.5 mm Turbo CLiRpath

Energy Parameter	Minimum Value	Maximum Value
(b) (4)		

2. REGULATORY HISTORY: Spectranetics originally gained approval for the proprietary CVX 300 Excimer Laser Coronary Angioplasty system under Premarket Approval #P910001, on 19 February 1993. CLiRpath laser catheters, for peripheral use as part of the CVX 300 system, were approved in on 27 April 2004 under 510(k) K040067.

Spectranetics seeks clearance for an additional catheter model, the CLiRpath 2.5 mm Turbo catheter (model 225-011), having an indication for use equivalent to that for previously approved CLiRpath laser catheter models.

3. Laser Catheter Construction and Assembly: Representative photos of one previously approved, representative predicate CLiRpath catheter (the 2.5 mm Extreme II, model 225-010), and the 2.5 mm Turbo catheter are included in Section 10 B, below.

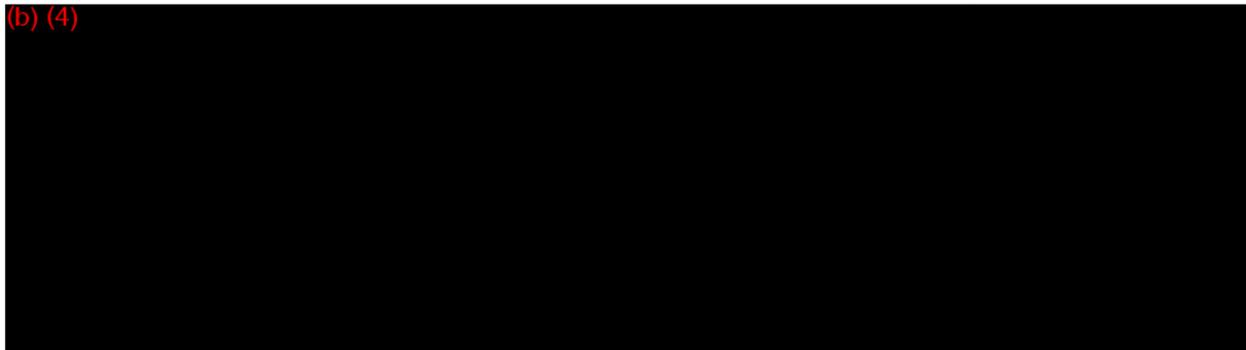


Table 10-A3a, below, summarizes the similarities between the specifications for the 2.5 mm Turbo catheter and the 2.5 mm Extreme II predicate catheter.

Continued next page

Table 10-A3a: 2.5 mm Turbo (225-011) and 2.5 mm Extreme II Product Specification Comparison

	2.5 mm Turbo 225-011	2.5 mm Extreme II 225-010
<b>SPECIFICATION</b>		
(b) (4)		

Table 10-A3b summarizes the materials of construction for the 2.5 mm Turbo catheter, and again provides a comparison to the 2.5 mm Extreme II catheter. (b) (4)



Continued next page

Table 10-A3b: 2.5 mm Turbo (225-011) and 2.5 mm Extreme II Product Comparison of Component Materials

	2.5 Turbo Catheter 3650-1150	2.5 Extreme II
Material	Composition	Composition
(b) (4)		

The designs and manufacturing techniques for the 2.5 Turbo peripheral catheter model were verified and validated in accord with the Quality System Regulation. Again, please refer to the Declaration of Conformity provided in Section 12.

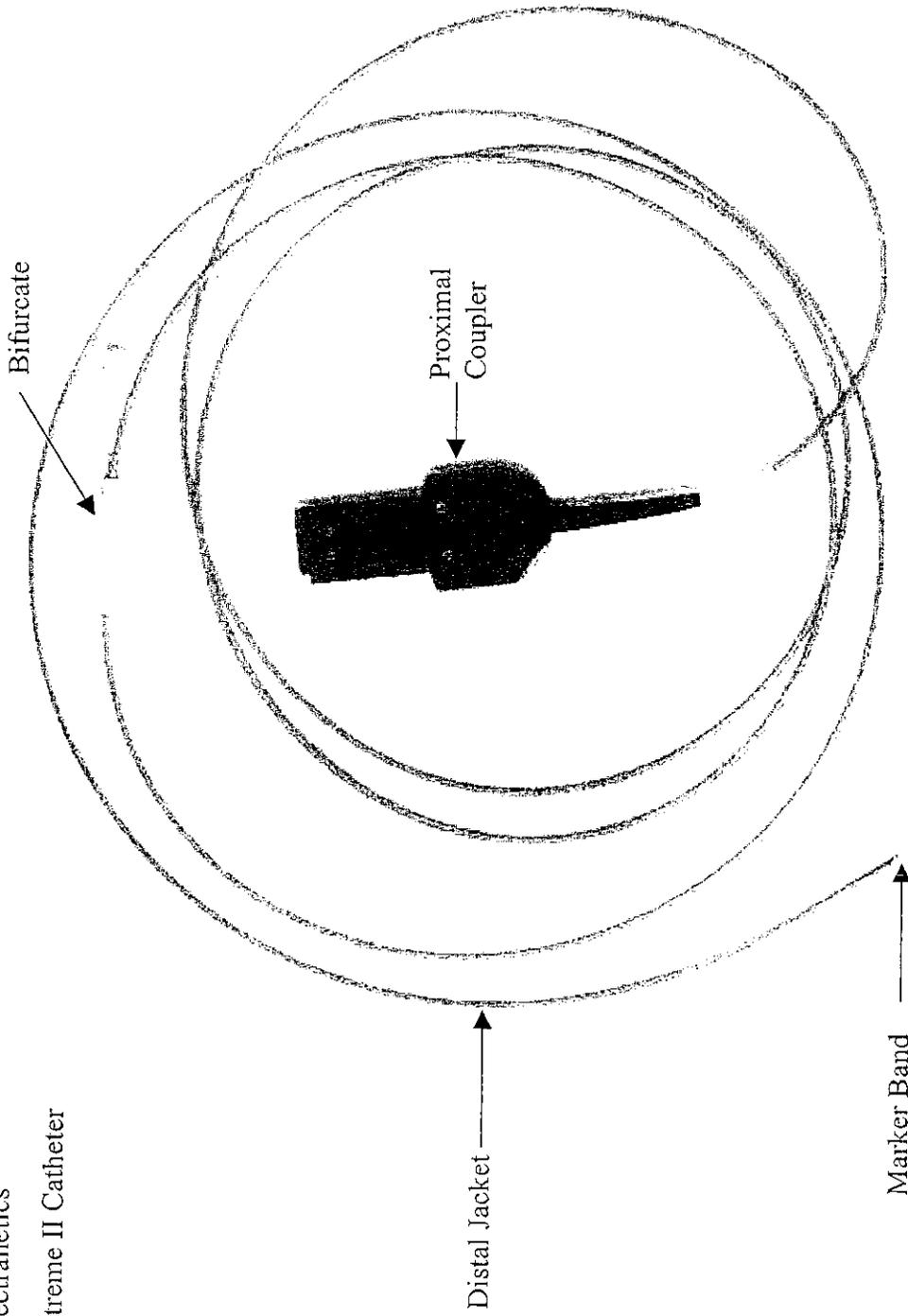
Continued next page

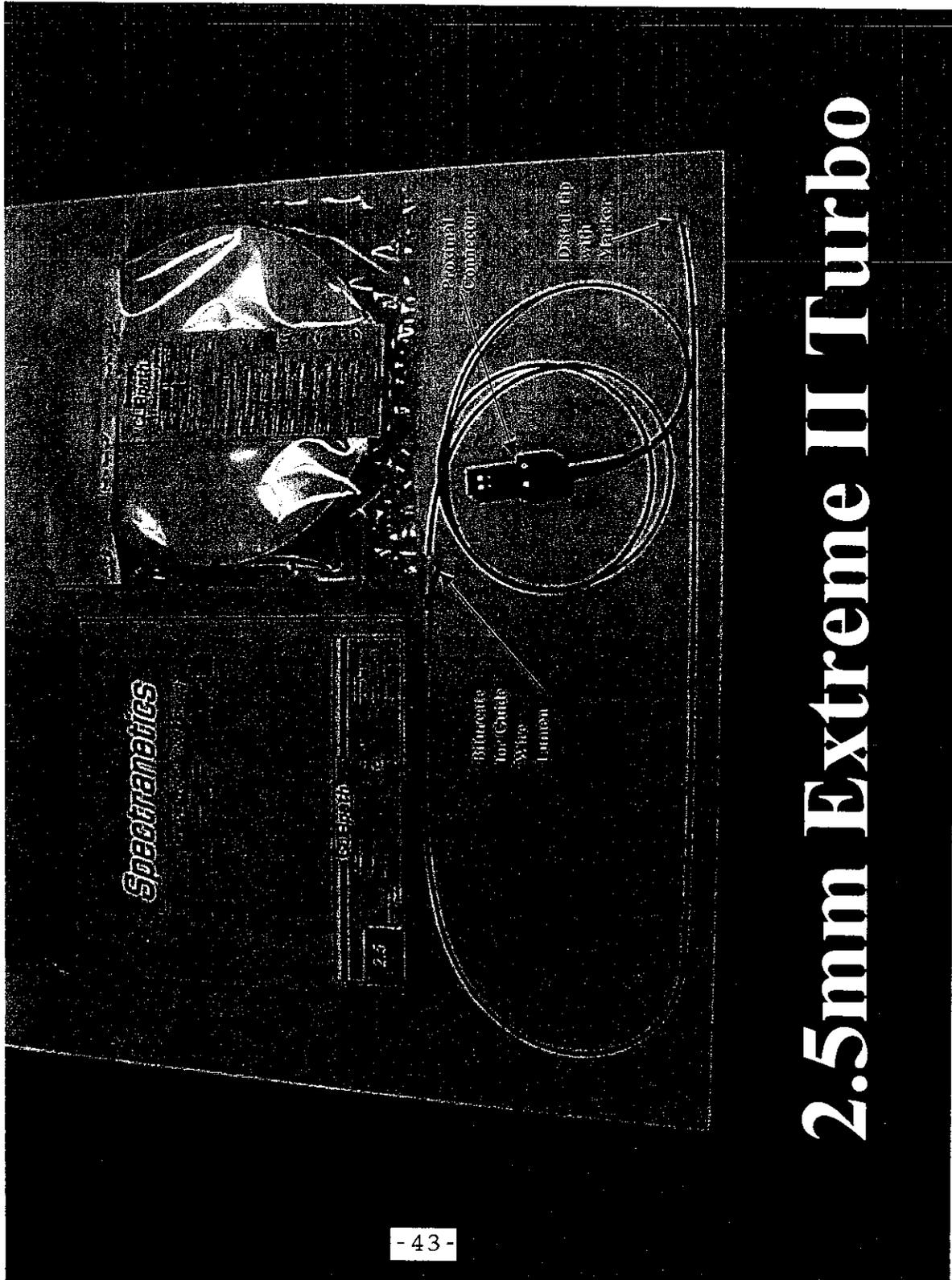
## **B. Photographs**

2.5 mm Extreme II CLiRpath Excimer Laser Catheter (225-010)

2.5 mm Turbo CLiRpath Excimer Laser Catheter (225-011)

Spectranetics  
Extreme II Catheter





## C. Assembly Drawings

### Drawings Representative of Previously Approved CLiRpath Catheters

Final Catheter Assembly 2.5 mm Extreme II, 3650-0163  
Production Flow Chart 2.5 mm Extreme II, 7020-0091

### Drawings of "New" 2.5 mm Turbo CLiRpath Catheter

Final Catheter Assembly 2.5 mm Turbo, 3650-1218  
Production Flow Chart 2.5 mm Turbo, 7020-0104



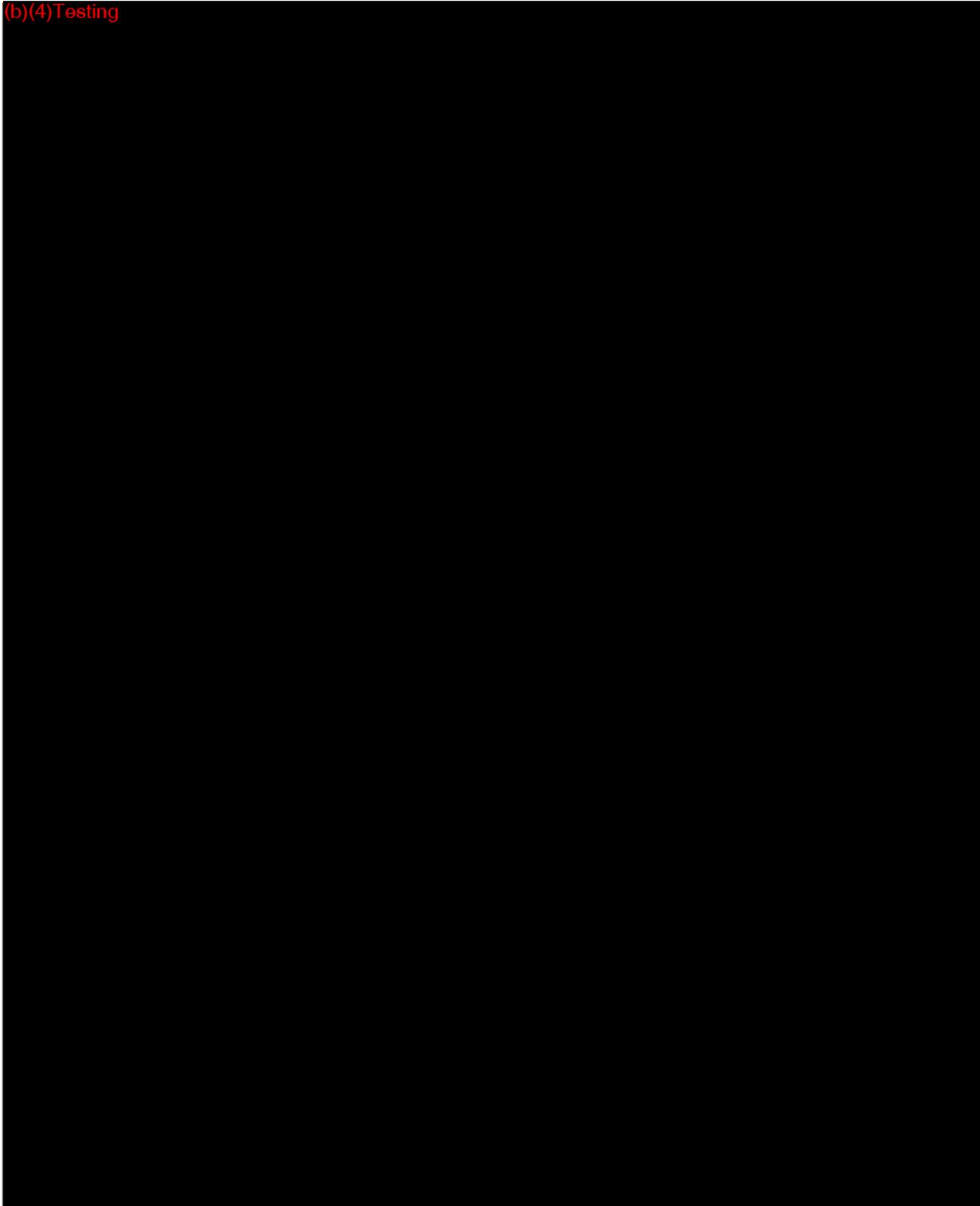






## D. Bench Testing

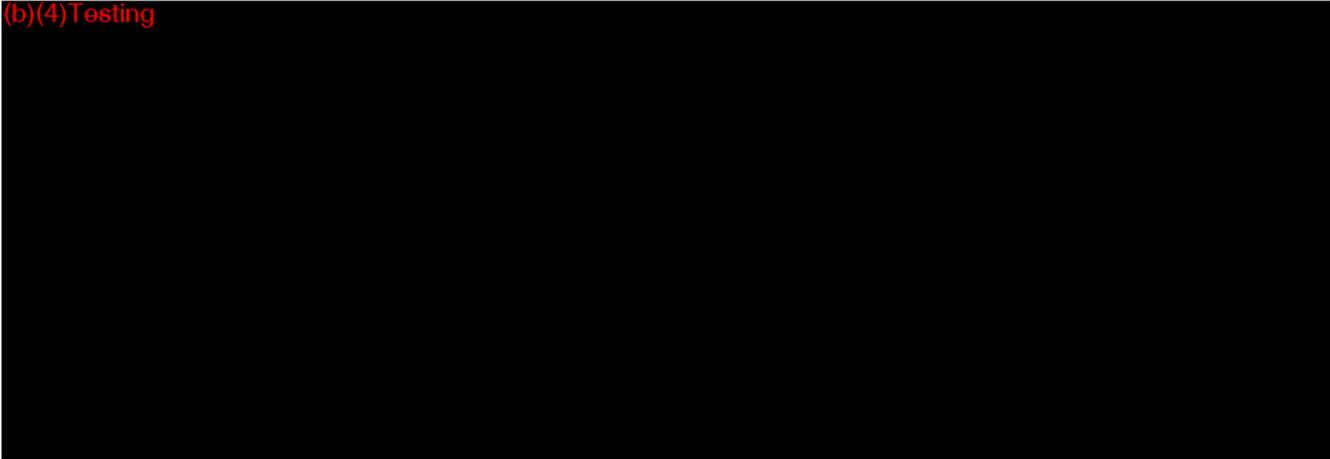
(b)(4) Testing



## E. Sterilization, Packaging, Shelf Life and Biocompatibility

### PRODUCT SHELF LIFE

(b)(4)Testing

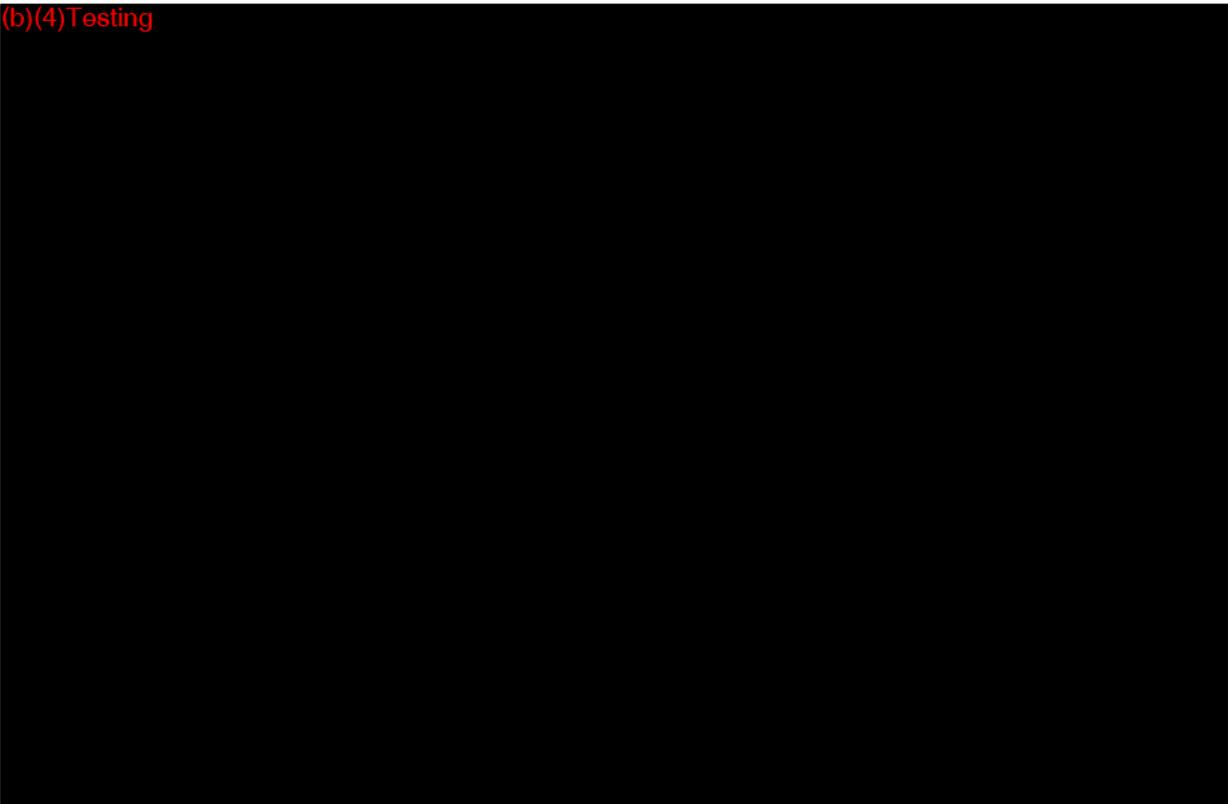


### NONCLINICAL TESTING (BIOCOMPATIBILITY, ENDOTOXINS, AND STERILIZATION)

1. Biocompatibility: (b)(4)Testing



(b)(4)Testing



(b)(4)Testing

The page contains two large black rectangular redaction boxes. The first box is at the top, starting with the text "(b)(4)Testing" in red. The second box is located below the first one.

Continued next page



(b)(4)Testing



2. Sterilization: (b)(4)Testing



(b)(4)Testing



## **11. Identification of Legally Marketed Predicate Device(s)**

The devices mentioned below serve as predicates to the Spectranetics 2.5 mm Turbo CLiRpath Excimer Laser Catheter, model 225-011.

Spectranetics CLiRpath catheters approved 27 April 2004, premarket clearance 510(k) K040067

**Declaration of Conformity to Recognized Standards for  
Spectranetics brand 2.5 mm Turbo CLiRpath Excimer Laser Catheter**

(b) (4)



## **12. PERFORMANCE STANDARDS AND DECLARATIONS OF MATERIAL IDENTITY WITH PREVIOUSLY APPROVED DEVICES**

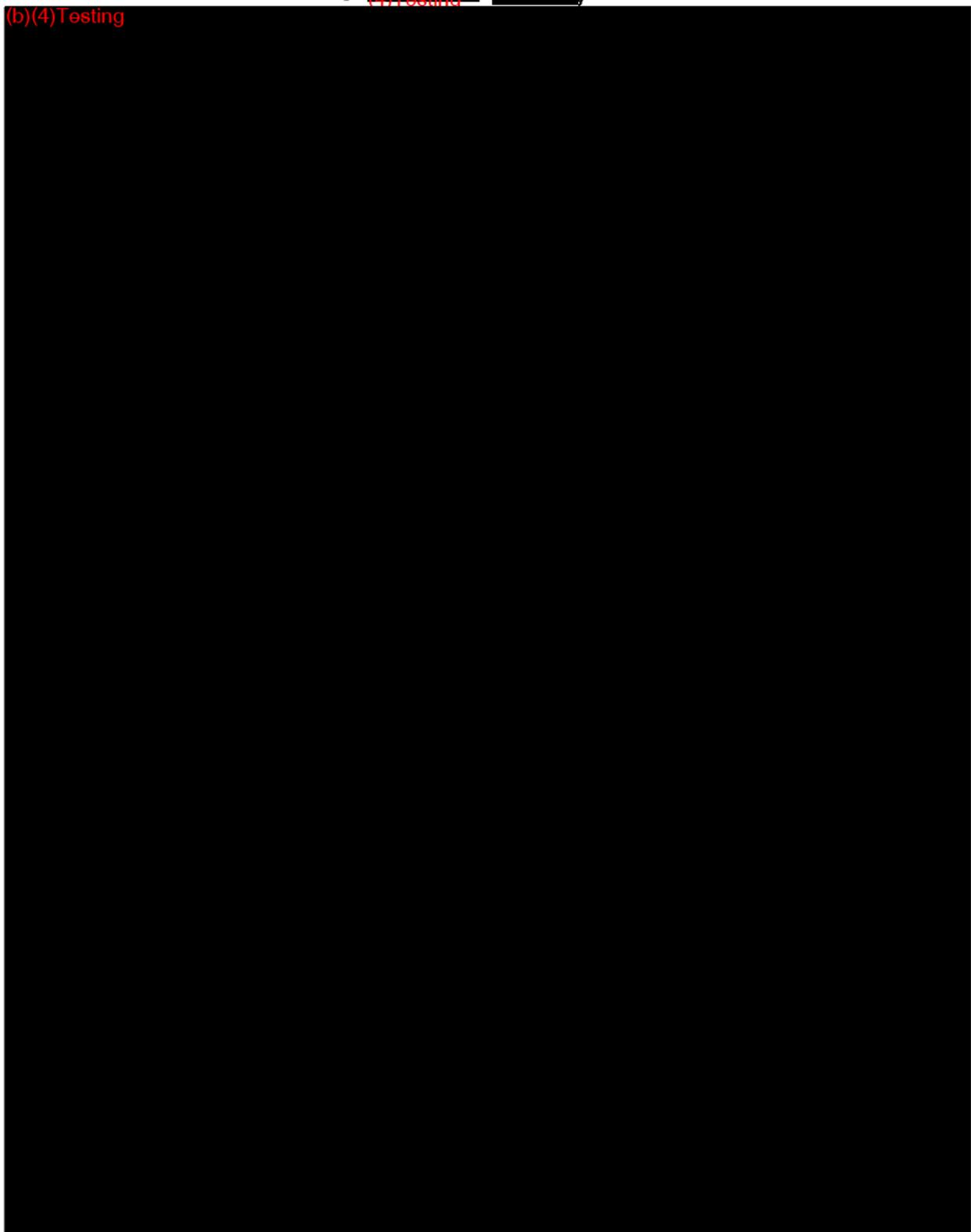
A Declaration of Conformity to Recognized Standards immediately follows this cover page, and declarations of material identity for purposes of biocompatibility follow the Declaration of Conformity.

### 13. SUMMARY OF *IN VIVO* DATA

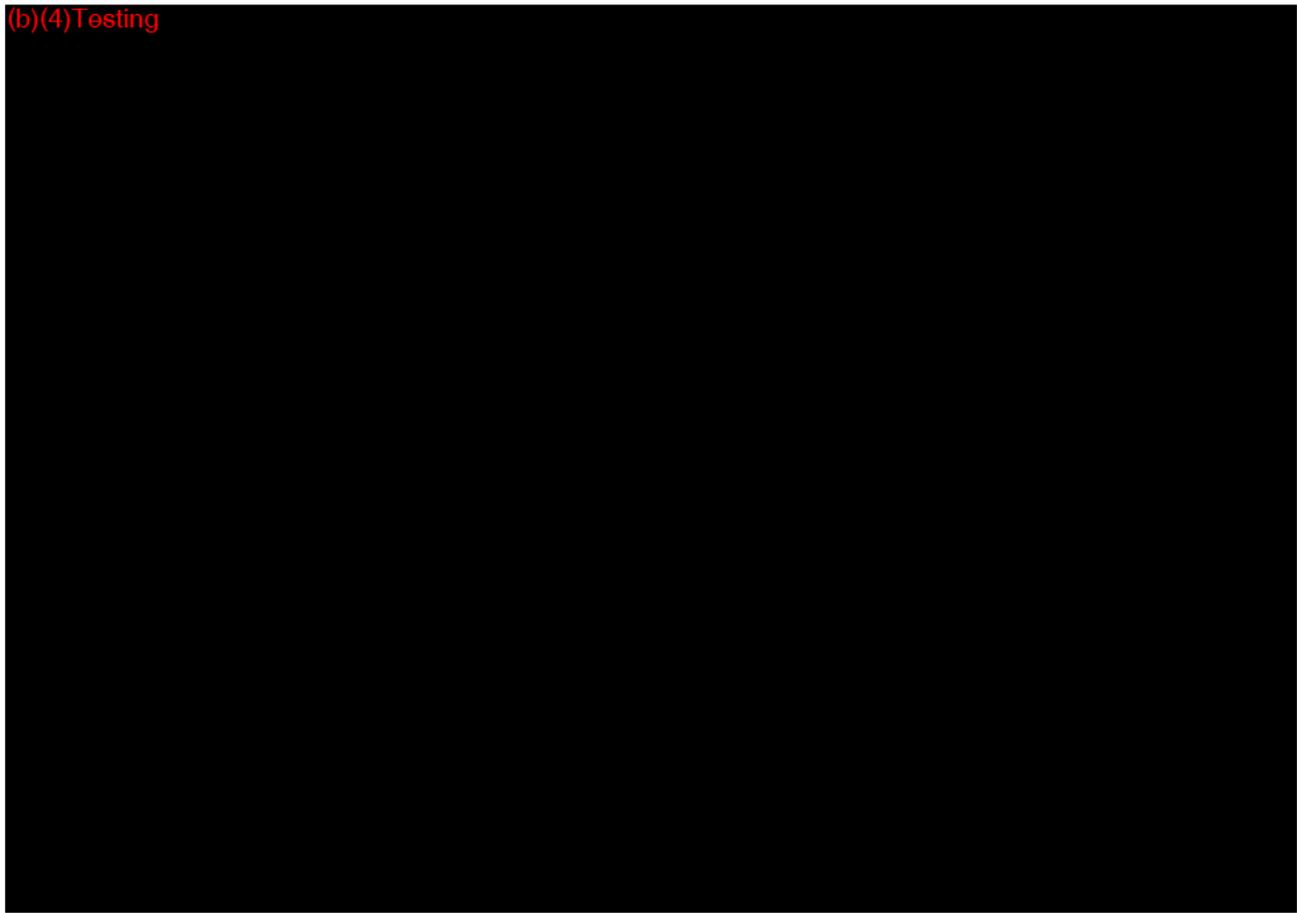
#### A. Animal Safety Study

(b) [Redacted] [Redacted]  
(4) Testing

(b)(4) Testing



(b)(4) Testing



**THIS PAGE DELIBERATELY LEFT BLANK**

## 14. APPENDICES

- A. IFU for Predicate Device, CLiRpath Excimer Laser Catheters
- B. Bench Testing Protocols and Data Reports
- C. Sterilization and Package Testing Protocols and Data Reports
- D. Animal Study [REDACTED]

A. IFU for Predicate Device, CLiRpath Excimer Laser Catheters

CLiRpath Excimer Laser Catheters (P/N 7030-0153)

## CLiRpath™ Excimer Laser Catheters

Cool Laser Revascularization for Peripheral Artery Therapy  
Extreme® (OTW) and Vitesse® (RX) Catheter Models

### Instructions For Use

#### Table of Contents

1. DESCRIPTION.....	1
2. INDICATIONS FOR USE.....	2
3. CONTRAINDICATIONS.....	2
4. WARNINGS.....	2
5. PRECAUTIONS.....	2
6. POTENTIAL ADVERSE EVENTS.....	2
7. CLINICAL STUDIES.....	3
8. INDIVIDUALIZATION OF TREATMENT.....	3
9. OPERATOR'S MANUAL.....	4
10. HOW SUPPLIED.....	4
10.1 STERILIZATION.....	4
10.2 INSPECTION PRIOR TO USE.....	4
10.3 PROCEDURE SET UP.....	4
10.4 COMPATIBILITY.....	4
11. DIRECTIONS FOR USE.....	4
12. COMPANY INFORMATION.....	6

#### 1. Description

Spectranetics CLiRpath™ excimer laser catheters are percutaneous intravascular devices constructed of multiple optical fibers arranged around a guidewire lumen.

For Extreme®, over the wire (OTW) catheters, a Luer adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the

appropriate sized guidewire (0.014", 0.016", 0.018", 0.025", and 0.035") see inset below.

For Vitesse®, rapid exchange (RX) catheters, the guidewire lumen is formed only through the last 9 cm of the distal tip, which has direct patient contact, and is concentric with the fiber array; see inset below.

For Vitesse®-E, rapid exchange (RX) eccentric catheters, the laser catheter consists of eccentrically aligned optical fibers and a stainless steel torque device encased within a polyester shaft. There are two major portions of the laser catheter shaft, the proximal portion which terminates at the laser connector, and the distal portion which terminates at the tip having direct patient contact. The torque device extends from the torque handle, located at the y-adapter, through the entire 140 cm of the distal portion of the catheter, and terminates in the distal tip. There is a mechanism within the torque handle which limits the turns to five full rotations in each direction. The torque handle also has an indicator displaying its range of motion. The laser catheter is packaged with the indicator in the center of its range (see inset below). The torque response is 6:1; six turns of the torque handle result in one 360° turn of the distal tip. A radiopaque marker band with radiolucent window is located on the distal tip of the laser catheter to aid localization within the coronary vasculature in conjunction with fluoroscopy.

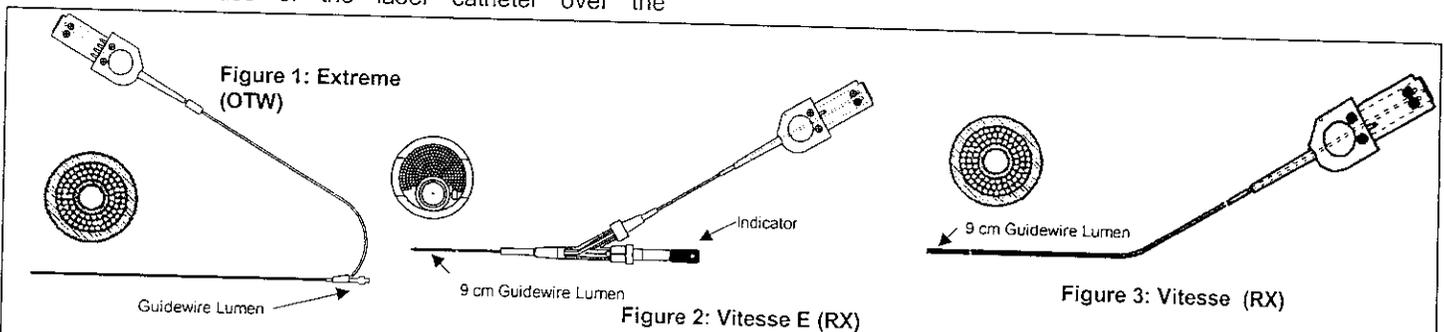


Table 1.1 CLiRpath Excimer Laser Catheter Models

Device OD Outer Diameter (mm)	Model Number	Max. Guidewire Lumen (in.)	Max. Tip Outside Diameter (in.)	Min. Tip Inside Diameter (in.)	Max. Shaft Diameter (in.)	Min Tail Tube Length (cm)	Min Working Length (cm)
<i>Extreme (OTW) Catheter Specifications</i>							
0.9 mm	110-001	0.014	0.038	0.0155	0.047	183	130
0.9 mm X80	110-002	0.014	0.038	0.0155	0.047	183	130
1.4 mm	114-001	0.014	0.056	0.017	0.056	183	131
1.7 mm	117-002	0.018	0.064	0.021	0.065	183	131
2.0 mm	120-001	0.018	0.077	0.021	0.076	183	131
2.0 mm II	220-006	0.018	0.0775	0.026	0.083	168	131
2.2 mm	222-005	0.035	0.088	0.037	0.089	168	120
2.3 mm II	223-001	0.035	0.092	0.039	0.094	168	120
2.5 mm	225-004	0.035	0.1	0.037	0.098	168	100
2.5 mm II	225-010	0.035	0.099	0.039	0.101	168	100
Device OD Outer Diameter (mm)	Model Number	Max. Guidewire Lumen (in.)	Max. Tip Outside Diameter (in.)	Min. Tip Inside Diameter (in.)	Max. Shaft Diameter (in.)	Min Tail Tube Length (cm)	Min Working Length (cm)
<i>Vitesse (RX) Catheter Specifications</i>							
0.9 mm	110-003	0.014	0.038	0.0155	0.049	183	131
0.9 mm X80	110-004	0.014	0.038	0.0155	0.049	183	131
1.4 mm	114-009	0.014	0.057	0.0175	0.062	183	131
1.7 mm	117-016	0.014	0.0685	0.0175	0.072	183	131
1.7 mm E	117-205	0.014	0.0685	0.0175	0.072	183	129
2.0 mm E	120-008	0.018	0.0785	0.0205	0.084	183	129
2.0 mm	120-009	0.014	0.08	0.0175	0.084	183	131

### Mechanism of Action for CLiRpath Catheters

The multifiber laser catheters transmit ultraviolet energy from the Spectranetics CVX-300® to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photo-ablate fibrous, calcific, and atheromatous lesions, thus recanalizing diseased vessels (photo ablation is the process by which energy photons cause molecular bond disruption at the cellular level without thermal damage to surrounding tissue). The Spectranetics laser catheters have a proprietary lubricious coating to ease their trackability through arteries.

### Glossary of Special Terms

*Retrograde Fashion* = In the direction opposite to blood flow.

*Antegrade Fashion* = In the direction of blood flow.

*Baseline Angiography* = Angiographic record of blood vessels.

*Contralateral Approach* = Arterial access by a crossover approach.

### 2. Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Note: Successful step-by-step passage of guide wires does not necessarily ensure relief of critical limb ischemia. Additional procedures may be required.

### 3. Contraindications

- No known contraindications.

### 4. Warnings

**Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.**

Spectranetics Excimer Laser Catheters require CVX-300® software versions 3.701 or 3.801 and higher.

When the laser catheter is in the body, it should be manipulated only while it is under fluoroscopic observation with radiographic equipment that provides high quality images.

The use of the CVX-300® Excimer Laser System is restricted to physicians who are trained in peripheral vascular intervention and who meet the training requirements listed below. These requirements include, but are not limited to:

1. Training of laser safety and physics.
2. Review of patient films of lesions that meet the indications for use.
3. A review of cases demonstrating the CLiRpath technique in occlusions that meet the indications for use.
4. A review of laser operation followed by a demonstration of the CVX-300® Excimer Laser System.
5. Hands on training with the CVX-300® Excimer Laser System and appropriate model.

6. A fully trained Spectranetics representative will be present to assist for a minimum of the first three cases.
7. Following the formal training session, Spectranetics will make available additional training if so requested by the physician, support personnel, the institution or Spectranetics.

### 5. Precautions

This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for **SINGLE USE ONLY** and must not be resterilized and/or reused.

Store in a cool, dry place. Protect from direct sunlight and high temperatures (*greater than 60°C or 140°F*).

The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised. Do not use catheter product if its "Use Before Date," found on package labeling, has been passed.

Before use, examine carefully all of the equipment to be used in the procedure for defects. Do not use any equipment if it is damaged.

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially biohazardous materials.

Read the Operator's Manual (7030-0035 or 7030-0068) thoroughly before operating the Excimer Laser System. Pay particular attention to the Warnings and Responsibility section of the manual which explains Notes, Cautions, and Warnings to be followed to ensure safe operation of the CVX-300®.

During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution's PTA protocol.

### 6. Adverse Events

Use of the Spectranetics CVX-300® Excimer Laser System may contribute to the following complications:

Events Observed during CLiRpath Clinical Studies (see Section 7)

Procedural Complications	Serious Adverse Events
<ul style="list-style-type: none"><li>• Spasm</li><li>• Major dissection</li><li>• Thrombus</li><li>• Distal embolization</li><li>• Perforation</li><li>• Other</li></ul>	<ul style="list-style-type: none"><li>• Death</li><li>• Reintervention</li><li>• ALI</li><li>• Major amputation</li><li>• Bypass Surgery</li><li>• Hematoma with Surgery</li></ul>

#### In-Hospital Complications

- Reocclusion
- Pseudoaneurysm
- Renal failure
- Bleeding

Potential Averse Events NOT Observed during CLiRpath Clinical Studies (see Section 7)

- Nerve Injury
- AV Fistula Formation
- Endarterectomy
- Infection
- Stroke
- Myocardial Infarction
- Arrhythmia

No long term adverse effects on the arterial vessel wall, due to peripheral excimer laser recanalization, are known at this time.

7. Clinical Studies

Data presented in this IFU comprise of a subset of patients pooled from three sources of consecutively treated patients presenting with Critical Limb Ischemia (CLI), who were poor surgical candidates:

- LACI Phase 2 – a subset of patients from a prospective IDE registry conducted in 2001-2002 at 14 sites in the US and Germany. The subset includes 26 limbs (in 25 patients) treated at 7 sites from the US and Germany in which the step by step CLiRpath laser recanalization technique was utilized. In 13 of these cases, step-by-step technique was utilized *ab initio*, that is, without first attempting to cross the occlusion with a guidewire.
- LACI Belgium - a subset of a 51-patient prospective registry conducted at 6 sites in Belgium. The subset includes 9 limbs (in 9 patients) treated at 3 sites in Belgium in which the step by step CLiRpath laser recanalization technique was utilized.
- Louisiana case series – a subset drawn from 62 cases included in an on-going data compilation by a single physician group in central Louisiana, the Cardiovascular Institute of the South (CIS). This subset of patients consists of 12 limbs (in 12 patients) in which the step by step CLiRpath laser recanalization technique was utilized.

Table 7.1 Procedure Information

Locations of vascular lesions (n=205)	
SFA	138 (67%)
Popliteal	23 (11%)
Infrapopliteal	42 (20%)

Angiographic Results (n=47 limbs)	
Lesions per limb	4.4
Average lesion length	73.4 ± 7.3 (mm)
Straight line flow to foot established	37 (79%)
Stent implanted	28 (60%)
Crossing Success Overall*	37 (79%)
Crossing Success after Guidewire Attempt	24/34 (71%)
Crossing Success <i>ab initio</i> Cases	13/13 (100%)
Procedure success**	34 (72%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

\*Crossing Success data has been stratified for step-by-step cases after conventional guidewire attempts in 24 limbs, and *ab initio* in 13 limbs.

\*\*Procedure success: ≤50% final residual stenosis

Table 7.2 Complications, n=47 limbs

Procedural Complications	
Spasm	1 (2%)
Major dissection	4 (9%)
Thrombus	1 (2%)
Distal embolization	3 (6%)
Perforation	3 (6%)
Other	5 (11%)
In-Hospital Complications	
Reocclusion	1 (2%)
Pseudoaneurysm	1 (2%)
Renal failure	1 (2%)
Bleeding	1 (2%)
Infection	0 (0%)
Other	0 (0%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

Table 7.3 Cumulative Serious Adverse Events (SAEs) through 6-month follow-up, for n=47 limbs

Death	3 (6%)
MI or Stroke	0 (0%)
Reintervention	6 (13%)
ALI	1 (2%)
Major amputation	2 (4%)
Bypass Surgery	2 (4%)
Endarterectomy	0 (0%)
Hematoma with Surgery	2 (4%)
Total	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

MI = Myocardial Infarction. ALI = Acute Limb Ischemia.

Table 7.4 Outcomes by Intention-to-Treat Analysis, n=47

Crossing Success	37 (79%)
Procedure Success	34 (72%)
Limb Salvage	40 (85%)
Death, any cause	3 (6%)
Any SAE	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

8. Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the CLiRpath device.

Use of CLiRpath devices may be considered after initial conventional crossing attempts with guidewires are unsuccessful due to:

- A rounded or eccentric occlusion stump deflecting the guidewire to a subintimal passage.
- The guidewire repeatedly being deflected into a large collateral branch flush with the occlusion stump.
- Calcification obstructing completion of guidewire passage within the obstructed lumen.

Additionally, recanalization of native arteries may be considered in patients presenting with occluded bypass grafts.

Patient selection and clinical techniques should be conducted according to instructions provided in Section 2, "Indications for Use," and Section 9, "Operator's Manual."

**9. Operator's Manual**

The devices described in this document can be operated within the following energy ranges on the CVX-300®:

Table 9.1 Energy Parameters

Device O.D.	Model No.	Fluence	Repetition Rate	Laser On/Off Time
<b>Extreme (OTW) Catheters</b>				
0.9 mm	110-001	30-60	25-40	5 sec on/10 sec off
0.9 mm X/80	110-002	30-80	25-80	10 sec on/5 sec off
1.4 mm	114-001	30-60	25-40	5 sec on/10 sec off
1.7 mm	117-002	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-001	30-60	25-40	5 sec on/10 sec off
2.0 mm	220-006	30-60	25-40	10 sec on/5 sec off
2.2 mm	222-005	30-60	25-40	5 sec on/10 sec off
2.3 mm	223-001	30-60	25-40	10 sec on/5 sec off
2.5 mm	225-004	30-50	25-40	5 sec on/10 sec off
2.5 mm	225-010	30-50	25-40	10 sec on/5 sec off
<b>Vitesse (RX) Catheters</b>				
0.9 mm	110-003	30-60	25-40	5 sec on/10 sec off
0.9 mm X/80	110-004	30-80	25-80	10 sec on/5 sec off
1.4 mm	114-009	30-60	25-40	5 sec on/10 sec off
1.7 mm	117-016	30-60	25-40	5 sec on/10 sec off
1.7 mm E	117-205	30-60	25-40	5 sec on/10 sec off
2.0 mm E	120-008	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-009	30-60	25-40	5 sec on/10 sec off

Recommended calibration settings: 45 Fluence, 25 Hz.

**10. How Supplied**

**10.1 Sterilization**

**For single use only.** Do not re-sterilize and/or reuse.

The Spectranetics laser catheters are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

**10.2 Inspection Prior to Use**

Before use, visually inspect the sterile package to ensure that seals have not been broken. All equipment to be used for the procedure, including the catheter, should be examined carefully for defects. Examine the laser catheter for bends, kinks or other damage. Do not use if it is damaged.

**10.3 Procedure Set Up**

Some or all of the following additional materials, which are not included in the laser catheter package, may be required for the procedure (these are single use items only—do not re-sterilize or reuse):

- Introducer sheaths and/or femoral guiding catheter(s) in the appropriate size and configuration to select the peripheral artery and facilitate largest laser catheter to be used.
- Tuohy-Borst "y" adapter or hemostatic valve(s).
- Sterile normal saline or Lactated Ringer's solution
- Standard contrast media
- 0.014", 0.016", 0.018", 0.025", or 0.035" guidewires

**10.4 Compatibility**

The Spectranetics' excimer laser catheter is designed and intended to be used exclusively with the Spectranetics CVX-300® Laser System.

Do not use in combination with any other laser system.

Guidewire Compatibility

See Catheter Specification Table in Section 1.

**11. Directions for Use**

Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the laser catheter from the tray while supporting the black laser connector, also known as the proximal end, proximal coupler, or proximal connector. Please note that the proximal end of the laser catheter connects only to the CVX-300®, and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the CVX-300® and position the laser catheter in the laser system extension pole. Calibrate the laser catheter following the instructions provided in the CVX-300® Operator's Manual (7030-0035 or 7030-0068).

1. Use standard femoral puncture technique to insert a 5 Fr. to 9 Fr. (depending on the largest interventional device to be used during treatment) introducer sheath into the common femoral artery in antegrade or retrograde fashion for contralateral approaches. Heparinize intravenously using the PTA protocol for heparinization.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014", 0.016", 0.018", 0.025", or 0.035" guidewire to the peripheral occlusion via the introducer sheath or guiding catheter.
4. Size and choose the laser catheter appropriately:

Table 11.1 Recommended Sizing

Catheter Size	Proximal Vessel Diameter
0.9 mm	≥1.5 mm
0.9 mm X/80	≥2.0 mm
1.4 mm	≥2.2 mm
1.7 mm	≥2.5 mm
2.0 mm	≥3.0 mm
2.2 mm	≥3.2 mm
2.3 mm	≥3.2 mm
2.5 mm	≥3.5 mm

Note: Choosing an eccentric laser catheter may be appropriate when lesion morphology or the location and tortuosity of the occluded vessel imply eccentric ablation would assist in following the true vessel lumen. Eccentric ablation may help avoid subintimal passage in such cases.

5. *This step applies only to Extreme catheter models.* Inject 5-10cc of heparinized saline or Lactated Ringer's solution through the laser catheter to flush the guidewire lumen. Attach a rotating hemostatic valve to the guidewire port into the guidewire lumen (See Figure 4). Introduce the distal tip of the Spectranetics laser catheter over the selected guidewire. Under fluoroscopic control, guide the laser catheter to the lesion. The laser catheter's radiopaque band marker indicates its position relative to the lesion.

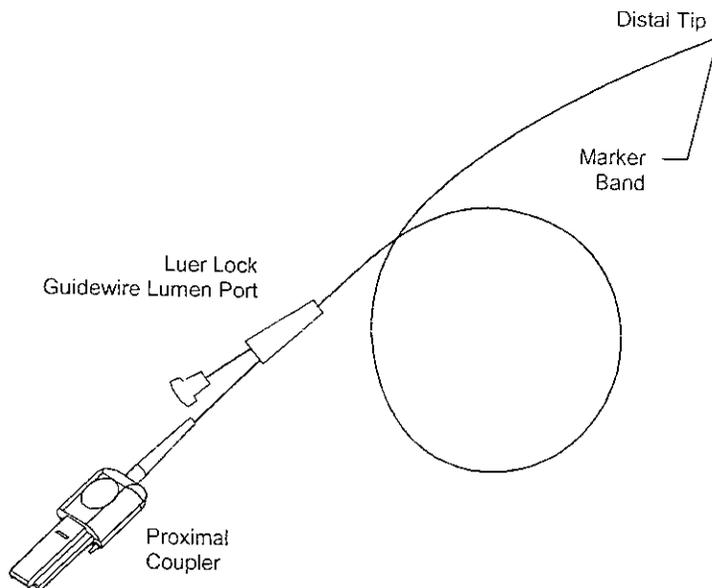


Figure 4 (not to scale)

11. Cross the last 3-5 mm of the occlusion and enter the patent distal vessel with the guidewire first, followed by the activated laser catheter over the wire.
12. Leaving the guidewire in position, pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.
13. Additional laser passes may be performed over the wire to achieve greater debulking of the lesion.

**Note**

If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter outer surface, inner lumen, and tip with heparinized saline to prevent blood from sticking. Blood remaining on the laser catheter may diminish the efficiency of the laser catheter.

14. There is no need to remove the laser catheter from the patient in order to increase or decrease either the fluence or pulse repetition rate; as the laser catheter was previously calibrated. Refer to the CVX-300® Excimer Laser System Operator's Manual, 7030-0035 or 7030-0068.

**Caution**

All patients should be monitored for blood pressure and heart rate during the procedure.

15. Following laser recanalization, perform follow up angiography and balloon angioplasty if needed. Stenting may be performed as required, in instances of acute recoil, major perforation, etc.
16. Recommended pharmacology follow up to be prescribed by the physician.

**EXCIMER LASER SALINE INFUSION PROTOCOL**

**Note**

This technique requires two operators. It is recommended that the primary physician operator advance the laser catheter and operate the laser system foot pedal. A scrub assistant should manage the saline infusion control syringe and (if appropriate) depress the fluoroscopy pedal.

- A. Before the laser procedure, warm a 500cc bag of 0.9% normal saline (NaCl), or Lactated Ringer's (LR) solution, to 37°C. It is not necessary to add heparin or potassium to the saline/LR solution. Connect the bag of warmed saline/LR to a sterile intravenous line and terminate the line at a port on a triple manifold.
- B. If applicable, cannulate the ostium of the artery with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter not have side holes.

6. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
7. Following confirmation of the laser catheter's position in contact with the target lesion and using normal saline or Lactated Ringer's solution:
  - a. Flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors,
  - b. Flush all residual contrast media from the lasing site and vascular structures adjacent to the lasing site, prior to activating the CVX-300® laser system.
  - c. Please refer to the Saline Infusion Protocol section of these Instructions for Use and perform saline flush and infusion per the instructions.
8. Depress the footswitch, activating the CVX-300®, and **slowly**, less than 1 mm per second, advance the laser catheter 2-3 mm into the total occlusion, allowing the laser energy to remove the desired material. Release the footswitch to deactivate the CVX-300®.

**Note**

Advancing the laser catheter through moderately calcified lesions may require more pulses of laser energy than fibrous atherosclerotic tissue.

9. Advance the guidewire beyond the distal tip of the laser catheter further into the occlusion, a few millimeters, and reactivate the laser as described in Step 8 above.
10. Continue in this step-by-step manner where the guidewire and then the laser catheter are advanced and activated (mm by mm) until the catheter reaches the last 3-5 mm of the occlusion.

- C. Under fluoroscopic guidance, advance the laser catheter into contact with the lesion. If necessary, inject contrast to help position the tip of the laser catheter. If contrast appears to have become entrapped between the laser catheter tip and the lesion, the laser catheter may be retracted slightly (1-2mm) to allow antegrade flow and contrast removal while flushing the system with saline/LR. **However, before lasing, ensure that the laser catheter tip is in contact with the lesion.**
- D. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline/LR through the manifold into the control syringe.
- E. Remove the original control syringe from the manifold and replace it with a fresh 20cc luer-lock control syringe. This new 20cc control syringe should be primed with saline/LR prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20cc control syringes.)
- F. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and introducer sheath or guide catheter, with at least 20-30cc of saline/LR (several syringes of saline/LR). When this initial flushing is completed, refill the 20cc control syringe with saline/LR.
- G. Under fluoroscopy, confirm that the tip of the laser catheter is in contact with the lesion (advance the laser catheter if necessary), but do not inject contrast.
- H. When the primary operator indicates that he/she is ready to activate the laser system, the scrub assistant should turn the manifold stopcock off to pressure and inject 10cc of saline/LR as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
- I. After the injection of the initial 10cc bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3cc/second. This portion of the saline/LR infusion is to displace and/or dilute the antegrade blood flow entering the laser ablation field. **At the instant the scrub assistant slows down the injection rate, the primary operator should activate the laser system by depressing the foot pedal and begin a lasing sequence.**
- J. Terminate the saline/LR injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20cc of saline/LR in preparation for the next lasing sequence.
- K. Each subsequent laser train should be preceded by a bolus of saline/LR and performed with continuous saline/LR infusion as described in steps H-J.
- L. If contrast is used to assess treatment results during the course of a laser treatment, repeat steps D - G **prior to** reactivation of the laser system (before activating the laser as described in steps H - J).

**Note**

Depending on which approach is used, antegrade or contralateral, saline/LR can be administered through the sheath (antegrade approach) or laser catheter inner lumen (contralateral approach). When the contralateral approach is used, smaller diameter guidewires are suggested to allow adequate saline/LR infusion at the treatment site.

**12. Company Information**

The company's standard one-year product warranty and remedy are exclusive and expressly in lieu of all other warranties expressed or implied either in fact or by operation of law, statutory or otherwise, including warranties of merchant ability and fitness for use or for any particular purpose and of all other liabilities or obligations on the part of the company relating in any way to the CVX-300<sup>®</sup> Excimer Laser System, whether arising from personal injury, property damage or otherwise. The company neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System. Notwithstanding the generality of the foregoing, (a) the company shall have no liability whatsoever for special, consequential, incidental or punitive damages of any kind arising out of the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System, and (b) the company's liability shall in no event exceed the original purchase price of the CVX-300<sup>®</sup> Excimer Laser System.

B. Bench Testing Protocols and Data Reports

(b) (4)

Design Verification Testing (b) (4)

Design Verification Testing (b) (4)

Design Verification Testing (b) (4)

(b) (4)

2.5 Turbo Coating Qualification— (b) (4)

(b) (4)





















































































































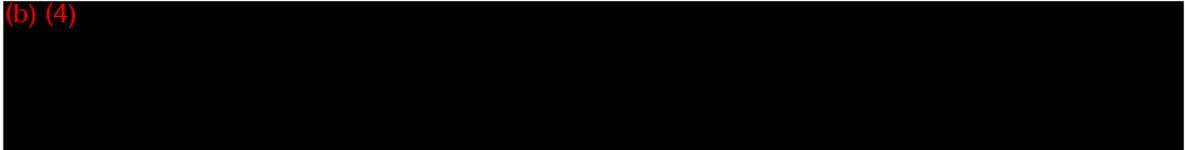
**THIS PAGE DELIBERATELY LEFT BLANK**

**THIS PAGE DELIBERATELY LEFT BLANK**

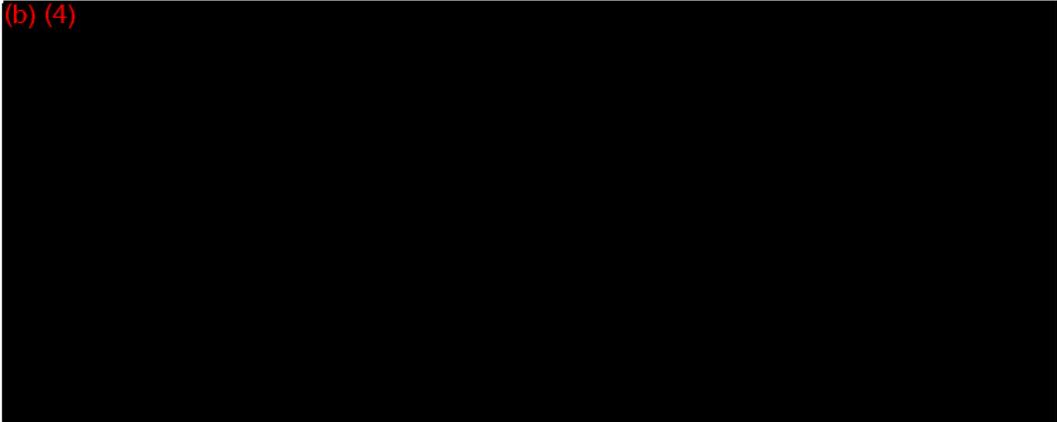
**THIS PAGE DELIBERATELY LEFT BLANK**

C. Sterilization and Package Testing Protocols and Data Reports

(b) (4)

A large black rectangular redaction box covering the majority of the page content.

(b) (4)

A large black rectangular redaction box covering the majority of the page content.



























**THIS PAGE DELIBERATELY LEFT BLANK**



























(b)(4) Testing













(b)(4) Testing























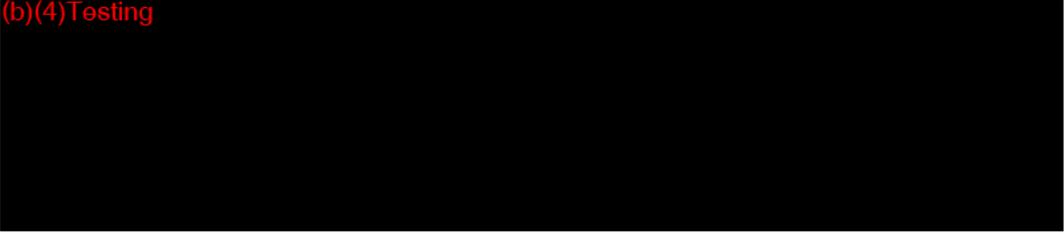








(b)(4) Testing

















































(b)(4) Testing



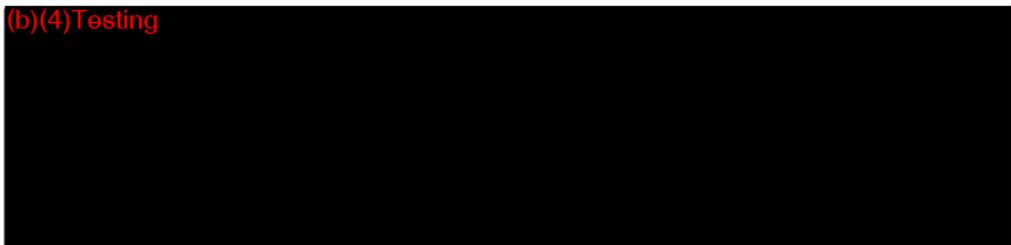








(b)(4) Testing





















(b)(4) Testing



1065































































DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Kon Cavanaugh  
Subject: 510(k) Number K043465/S<sup>2</sup>  
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.).

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):  
 No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

Predicate Product Code with class: MCW Class II Additional Product Code(s) with panel (optional):

Review: [Signature] P003 8/16/05  
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] for BDE 8/17/05  
(Division Director) (Date)

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		/
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?	/	
5. Is the product a device?	/	/
6. Is the device exempt from 510(k) by regulation or policy?	/	
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		/
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		/
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: Ken <sup>K 043465</sup> Caravanaugh  
 Division/Branch: DCD/PVDB  
 Device Name: 2.5mm Turbo Excimer Laser Catheter  
 Product To Which Compared (510(K) Number If Known): 040067

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

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

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

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics: *Different amount of laser output; hydrophilic coating*
6. Explain how new characteristics could or could not affect safety or effectiveness: *Increased laser output could injure vessels; coating could adversely affect handling characteristics*
7. Explain how descriptive characteristics are not precise enough: *Cannot evaluate laser performance or handling via description*
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: *Laser performance & handling can be assessed through preclinical testing*
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *Data are comparable to those of predicate*

ATTACH ADDITIONAL SUPPORTING INFORMATION



---

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

**Date:** August 16, 2005  
**From:** Kenneth J. Cavanaugh, Jr., Ph.D., Biomedical Engineer  
FDA/CDRH/ODE/DCD/PVDB  
**510(k) Number:** K043465 S002

**Device Name:** 2.5 mm Turbo Excimer Laser Catheter (Model 225-011)  
**Product Code:** 74 MCW – Catheter, Peripheral, Atherectomy      **CFR Code:** 870.5150

**Manufacturer:** Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, CO 80907-5186

**Contact:** Michael J. Ryan, RA Manager  
Phone: (719) 442-2433      Fax: (719) 442-2481  
Email: [neil.burris@spectranetics.com](mailto:neil.burris@spectranetics.com)

or

Adrian Elfe  
Phone: (719) 442-2425  
Email: [adrianelfe@spectranetics.com](mailto:adrianelfe@spectranetics.com)

**Predicate Devices:** K040067 – Spectranetics CLiRpath Excimer Laser Catheters

---

**I. Introduction**

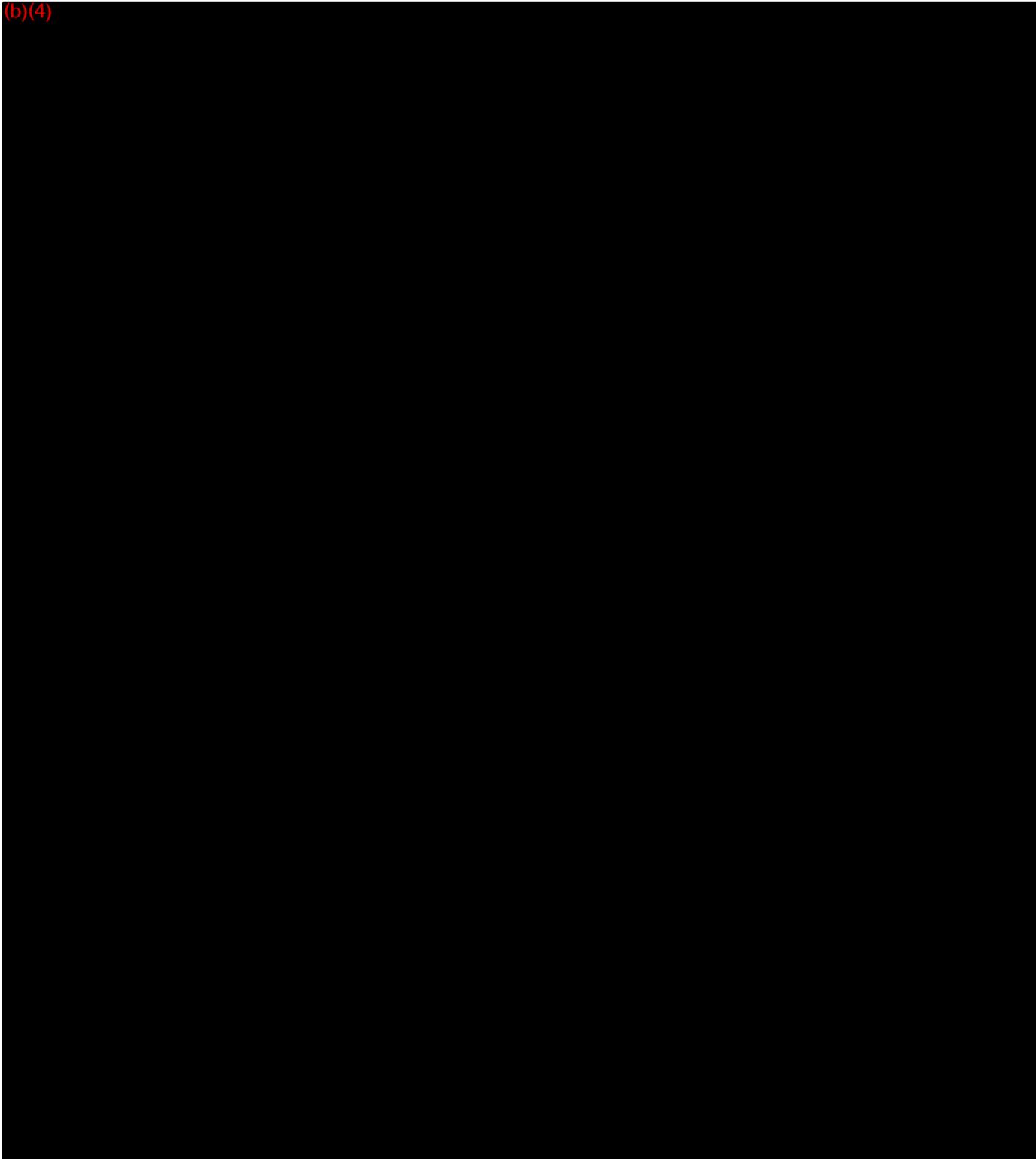
This premarket notification submission is for a new device, the 2.5 mm Turbo Excimer Laser Catheter, which would be a Class II device upon clearance. The manufacturer wishes to add this new catheter model to their existing CLiRpath Excimer Laser Catheter line. The currently marketed CLiRpath catheters were cleared under premarket notification K040067 and will serve as the predicate devices for the new Turbo catheter model. The new device has the same indications as the previously cleared catheters but incorporates several design changes, most notably the addition of a lubricious coating, a greater number of optic fibers, and continuous “on” capability.

The original 510(k) submission was put on hold on January 31, 2005 and subsequently on August 5, 2005, pending the submission of additional information. With this supplement, the applicant has attempted to address each of FDA’s previously identified deficiencies. Prior to submission of this supplement, William Riemenschneider, Biologist, and I spoke with the sponsor on 8/5/05 to discuss the applicant’s proposed strategy for addressing the outstanding issues.

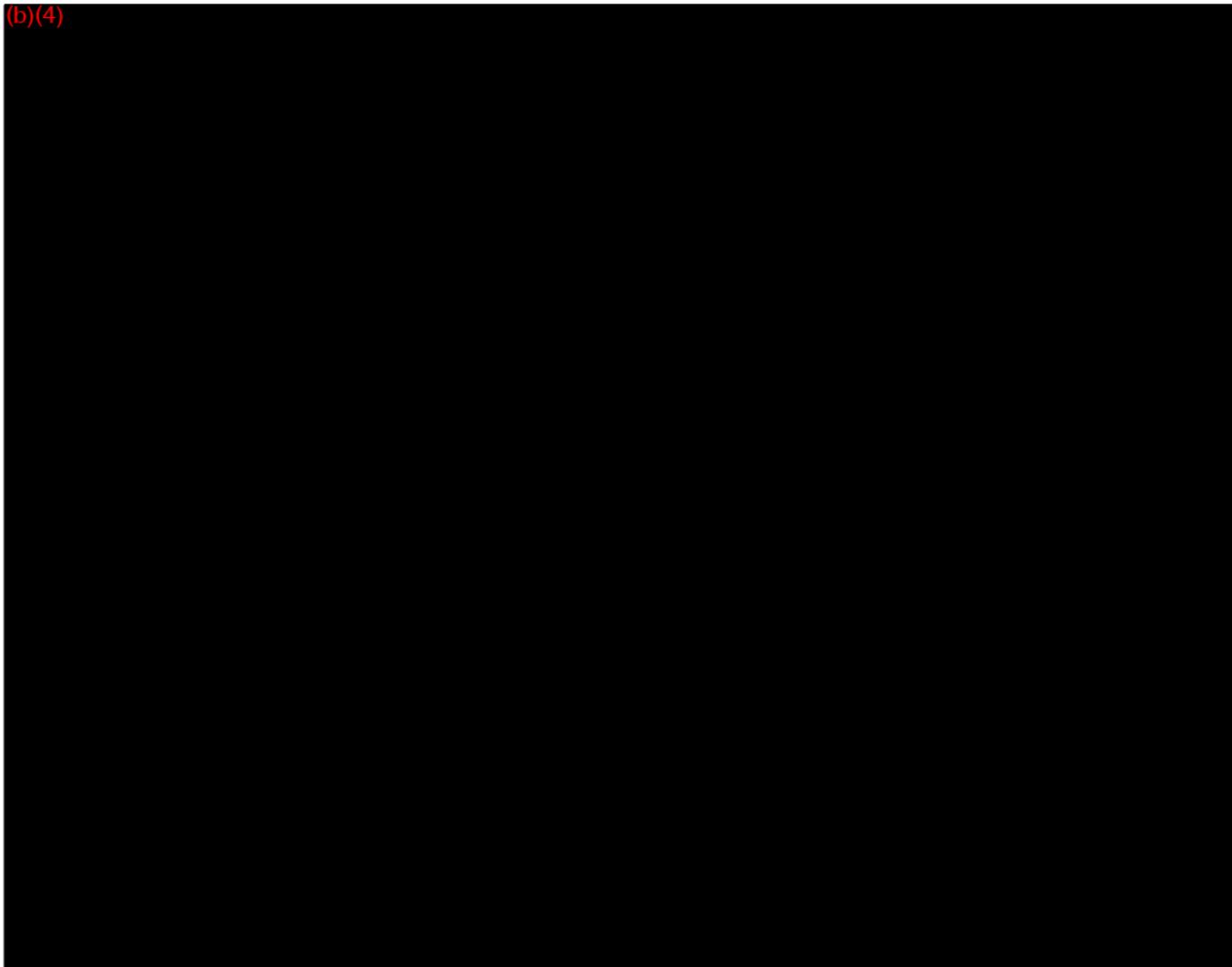
**II. Review of Submission**

Each of the deficiencies identified in FDA's 8/5/05 letter is presented below, followed by a review and summary of the applicant's response. I discussed the applicant's response to deficiency #1 with Mr. Riemenschneider, who originally formulated this deficiency.

(b)(4)



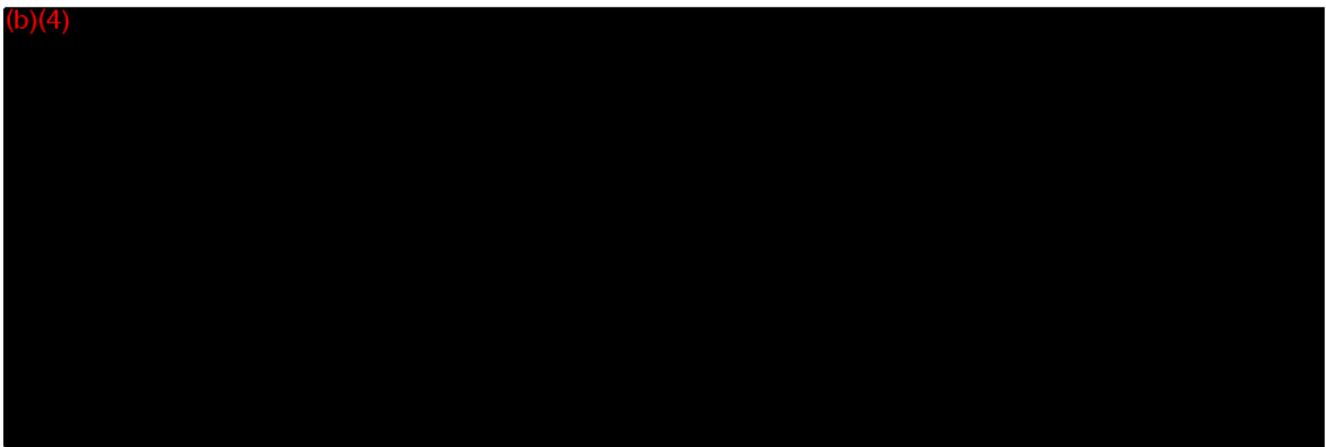
(b)(4)



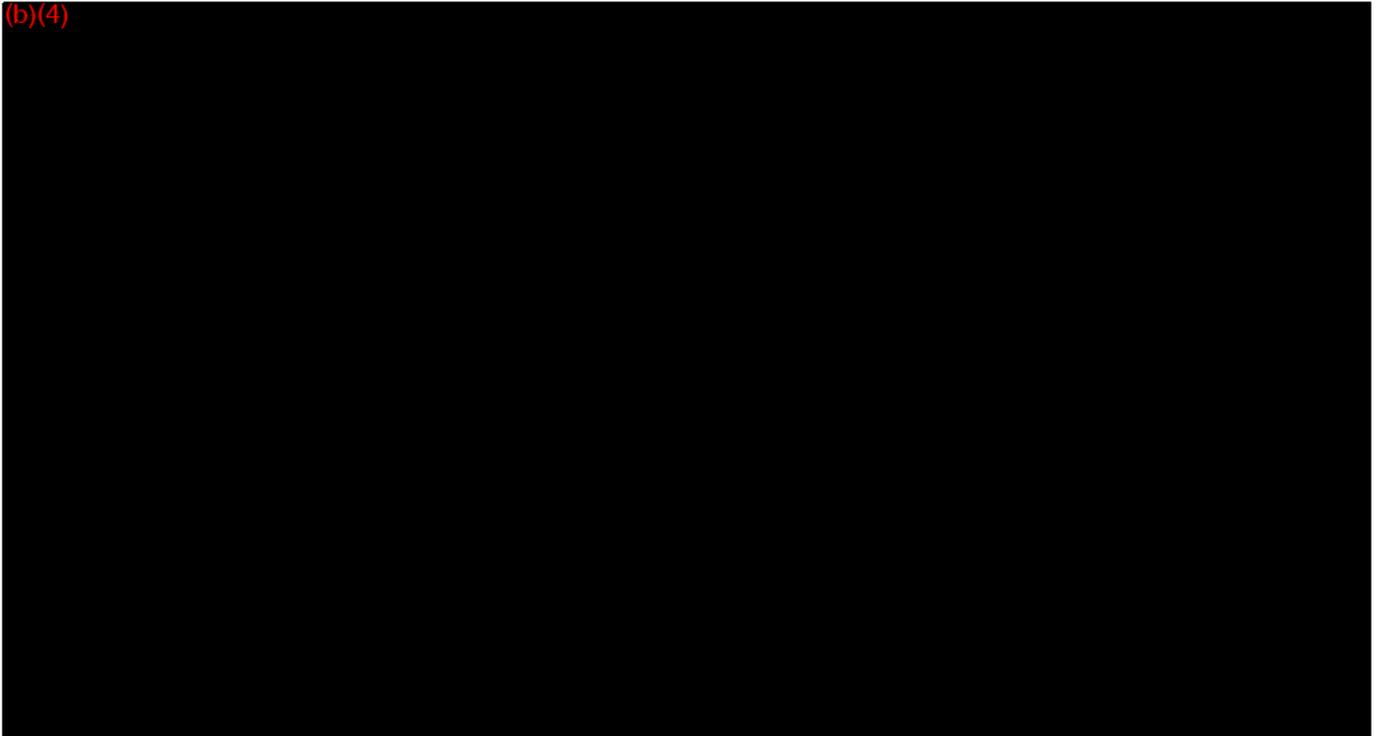
There are no outstanding concerns related to the animal study results.  
**Acceptable response.**

*Bench Testing*

(b)(4)

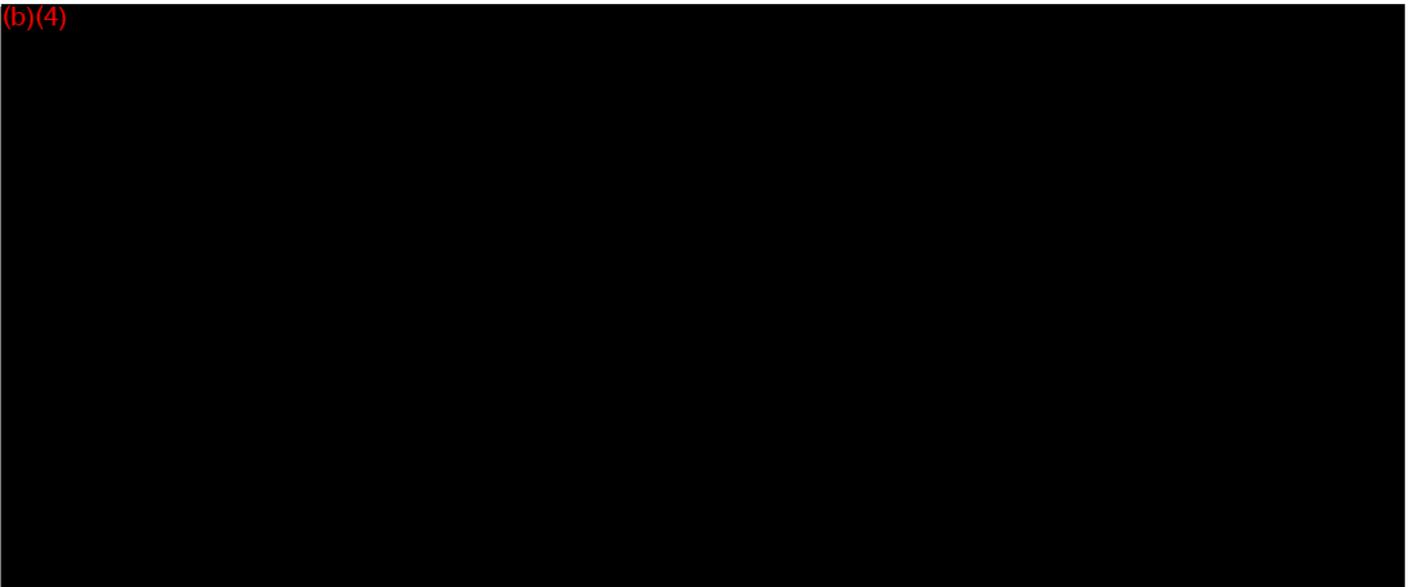


(b)(4)



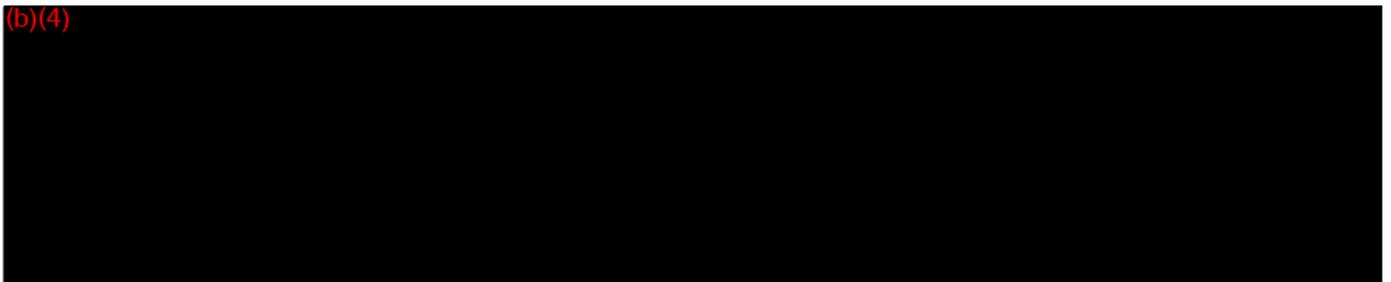
**Acceptable response.**

(b)(4)



**Acceptable response.**

(b)(4)



(b)(4)



**Acceptable response.**

**Reviewer Recommendation: Substantially Equivalent - SE**

  
\_\_\_\_\_  
Kenneth J. Cavanaugh, Jr., Ph.D.  
Biomedical Engineer  
Peripheral Vascular Devices Branch

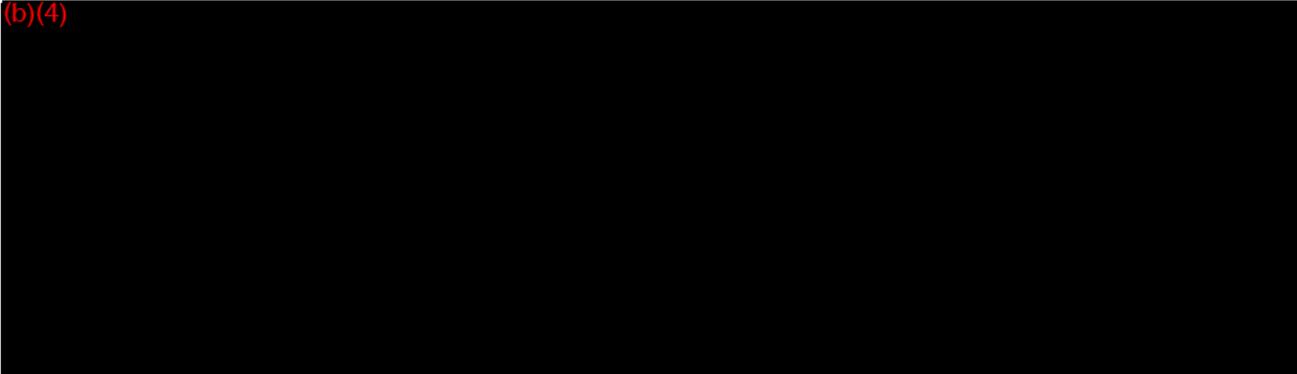
  
\_\_\_\_\_  
Chief  
Peripheral Vascular Devices Branch

**Cavanaugh, Kenneth J**

---

From: Neil.Burris@spectranetics.com  
Sent: Tuesday, August 16, 2005 12:51 PM  
To: Cavanaugh, Kenneth J  
Subject: RE: 2.5 mm Turbo CLiRpath Catheter K043465

(b)(4)



Neil

Neil Burris  
Clinical Data  
Spectranetics Corp.  
719 442 2456 direct  
1 800 633 0960 ext 456  
719 442 2481 fax

"Cavanaugh,  
Kenneth J"  
<KJC@CDRH.FDA.GOV>

08/16/2005 10:12  
AM

To  
"Neil.Burris@spectranetics.com"  
<Neil.Burris@spectranetics.com>

CC  
Kelly\_Elliott/Spectranetics/US  
<Kelly\_Elliott/Spectranetics/US@SPECTRANETICS.COM>,  
"Adrian.Elfe@spectranetics.com"  
<Adrian.Elfe@spectranetics.com>,  
Mike\_Ryan/notesadmin/US  
<Mike\_Ryan/notesadmin/US@spectranetics.com>

Subject  
RE: 2.5 mm Turbo CLiRpath Catheter  
K043465

Neil,

(b)(4)



(b)(4)



Thanks,

Ken

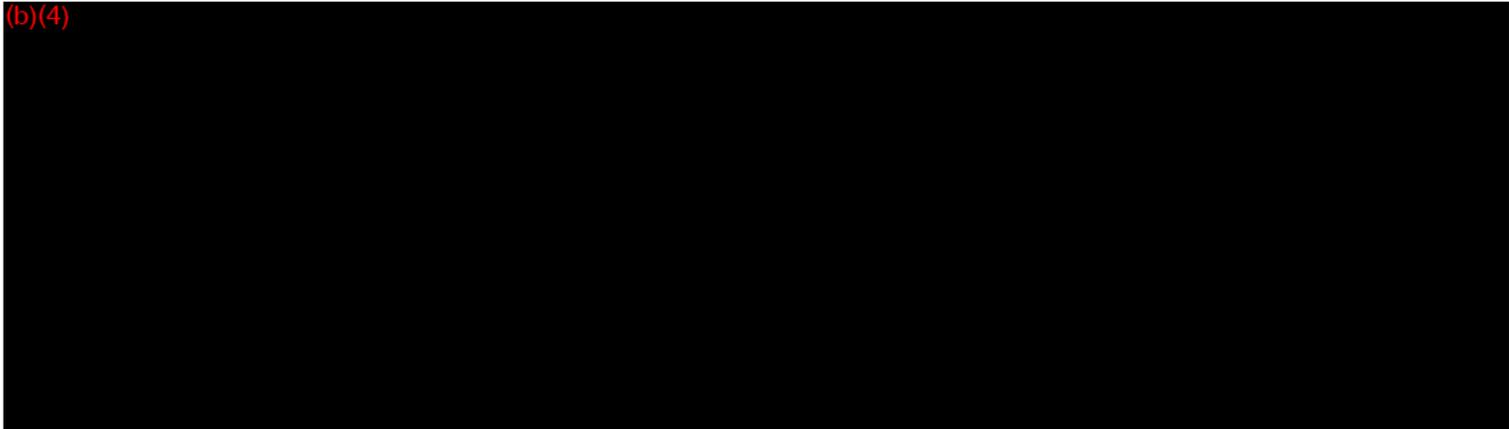
Kenneth J. Cavanaugh, Jr., Ph.D.  
Biomedical Engineer  
Peripheral Vascular Devices Branch  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
Phone: (301) 443-8517, ext. 170  
Fax: (301) 594-3076

-----Original Message-----

From: Neil.Burris@spectranetics.com [mailto:Neil.Burris@spectranetics.com]  
Sent: Tuesday, August 16, 2005 11:35 AM  
To: kjc@cdrh.fda.gov  
Cc: Kelly\_Elliott/Spectranetics/US@SPECTRANETICS.COM;  
Adrian.Elfe@spectranetics.com; Mike\_Ryan/notesadmin/US@spectranetics.com  
Subject: 2.5 mm Turbo CLiRpath Catheter K043465

Ken,

(b)(4)



Regards,

Neil

Neil Burris  
Clinical Data  
Spectranetics Corp.  
719 442 2456 direct  
1 800 633 0960 ext 456  
719 442 2481 fax

Do not use in combination with any other laser system.

**Guidewire Compatibility**

See Catheter Specification Table in Section 1.

**11. Directions for Use**

Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the laser catheter from the tray while supporting the black laser connector, also known as the proximal end, proximal coupler, or proximal connector. Please note that the proximal end of the laser catheter connects only to the CVX-300®, and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the CVX-300® and position the laser catheter in the laser system extension pole. Calibrate the laser catheter following the instructions provided in the CVX-300® Operator's Manual (7030-0035 or 7030-0068).

1. Use standard femoral puncture technique to insert a 5 Fr. to 9 Fr. (depending on the largest interventional device to be used during treatment) introducer sheath into the common femoral artery in antegrade or retrograde fashion for contralateral approaches. Heparinize intravenously using the PTA protocol for heparinization.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014", 0.016", 0.018", 0.025", or 0.035" guidewire to the peripheral occlusion, via the introducer sheath or guiding catheter.
4. Size and choose the laser catheter appropriately:

Table 11.1 Recommended Sizing

Catheter Size	Proximal Vessel Diameter
0.9 mm	≥2.0 mm
1.4 mm	≥2.2 mm
1.7 mm	≥2.5 mm
2.0 mm	≥3.0 mm
2.3 mm	≥3.2 mm
2.5 mm	≥3.5 mm

5. *This step applies only to Extreme catheter models.* Inject 5-10cc of heparinized saline or Lactated Ringer's solution through the laser catheter to flush the guidewire lumen. Attach a rotating hemostatic valve to the guidewire port into the guidewire lumen (See Figure 3). Introduce the distal tip of the Spectranetics laser catheter over the selected guidewire. Under fluoroscopic control, guide the laser catheter to the lesion. The laser catheter's radiopaque band marker indicates its position relative to the lesion.

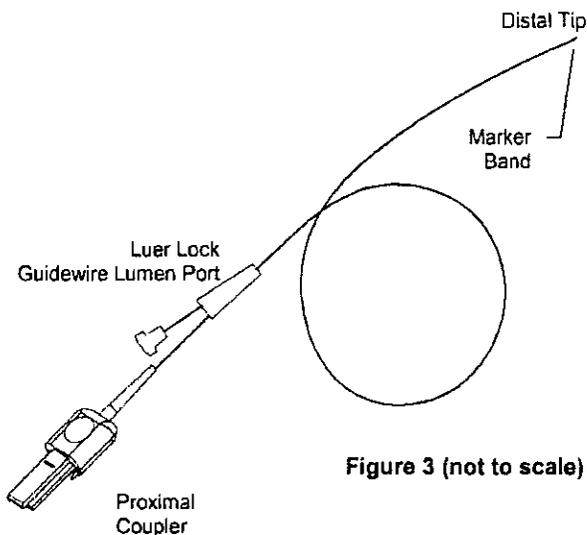


Figure 3 (not to scale)

**Note:**  
 During use within the body, similar to any device used for vascular intervention, always monitor Laser Catheter movement and the radiopaque tip marker position with fluoroscopy. The movement and rate of advancement of the catheter distal tip should correspond directly with the rate of advancement being applied to the proximal shaft of the catheter.

If corresponding movement is not apparent, reassess the lesion morphology, the laser energy being applied and the status of support equipment prior to continued treatment.

In the absence of apparent catheter movement, care should be taken not to deliver excessive laser energy.

6. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
7. Following confirmation of the laser catheter's position in contact with the target lesion and using normal saline or Lactated Ringer's solution:
  - a. Flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors,
  - b. Flush all residual contrast media from the lasing site and vascular structures adjacent to the lasing site, prior to activating the CVX-300® laser system.
  - c. Please refer to the Saline Infusion Protocol section of these Instructions for Use and perform saline flush and infusion per the instructions.
8. Depress the footswitch, activating the CVX-300®, and slowly, less than 1 mm per second, advance the laser catheter 2-3 mm into the total occlusion, allowing the laser energy to remove the desired material. Release the footswitch to deactivate the CVX-300®.

## EXCIMER LASER SALINE INFUSION PROTOCOL

### Note

Advancing the laser catheter through moderately calcified lesions may require more pulses of laser energy than fibrous atherosclerotic tissue.

9. When using CliRpath® Turbo models, the CVX-300® laser system will continuously deliver energy as long as the footswitch is depressed. The length of the laser train is controlled by the operator. It is generally recommended not to exceed 20 seconds of continuous lasing.
10. Advance the guidewire beyond the distal tip of the laser catheter further into the occlusion, a few millimeters, and reactivate the laser as described in Step 8 above.
11. Continue in this step-by-step manner where the guidewire and then the laser catheter are advanced and activated (mm by mm) until the catheter reaches the last 3-5 mm of the occlusion.
12. Cross the last 3-5 mm of the occlusion and enter the patent distal vessel with the guidewire first, followed by the activated laser catheter over the wire.
13. Leaving the guidewire in position, pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.
14. Additional laser passes may be performed over the wire to achieve greater debulking of the lesion.

### Note

If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter outer surface, inner lumen, and tip with heparinized saline to prevent blood from sticking. Blood remaining on the laser catheter may diminish the efficiency of the laser catheter.

If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the CVX-300®. The fluence and repetition rates can be increased in order to advance. To avoid the potential of heat build-up, the catheter must be advanced while lasing.

15. There is no need to remove the laser catheter from the patient in order to increase or decrease either the fluence or pulse repetition rate; as the laser catheter was previously calibrated. Refer to the CVX-300® Excimer Laser System Operator's Manual, 7030-0035 or 7030-0068.

### Caution

All patients should be monitored for blood pressure and heart rate during the procedure.

16. Following laser recanalization, perform follow up angiography and balloon angioplasty if needed. Stenting may be performed as required, in instances of acute recoil, major perforation, etc.
17. Recommended pharmacology follow up to be prescribed by the physician.

### Note

This technique requires two operators. It is recommended that the primary physician operator advance the laser catheter and operate the laser system foot pedal. A scrub assistant should manage the saline infusion control syringe and (if appropriate) depress the fluoroscopy pedal.

- A. Before the laser procedure, warm a 500cc bag of 0.9% normal saline (NaCl), or Lactated Ringer's (LR) solution, to 37°C. It is not necessary to add heparin or potassium to the saline/LR solution. Connect the bag of warmed saline/LR to a sterile intravenous line and terminate the line at a port on a triple manifold.
- B. If applicable, cannulate the ostium of the artery with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter not have side holes.
- C. Under fluoroscopic guidance, advance the laser catheter into contact with the lesion. If necessary, inject contrast to help position the tip of the laser catheter. If contrast appears to have become entrapped between the laser catheter tip and the lesion, the laser catheter may be retracted slightly (1-2mm) to allow antegrade flow and contrast removal while flushing the system with saline/LR. **However, before lasing, ensure that the laser catheter tip is in contact with the lesion.**
- D. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline/LR through the manifold into the control syringe.
- E. Remove the original control syringe from the manifold and replace it with a fresh 20cc luer-lock control syringe. This new 20cc control syringe should be primed with saline/LR prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20cc control syringes.)
- F. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and introducer sheath or guide catheter, with at least 20-30cc of saline/LR (several syringes of saline/LR). When this initial flushing is completed, refill the 20cc control syringe with saline/LR.
- G. Under fluoroscopy, confirm that the tip of the laser catheter is in contact with the lesion (advance the laser catheter if necessary), but do not inject contrast.
- H. When the primary operator indicates that he/she is ready to activate the laser system, the scrub assistant should turn the manifold stopcock off to pressure and inject 10cc of saline/LR as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
- I. After the injection of the initial 10cc bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3cc/second. This portion of the saline/LR infusion is to displace and/or dilute the antegrade blood flow entering

the laser ablation field. At the instant the scrub assistant slows down the injection rate, the primary operator should activate the laser system by depressing the foot pedal and begin a lasing sequence.

- J. The length of the laser train is controlled by the operator. It is generally recommended not to exceed 20 seconds of continuous lasing. Saline/LR must be infused throughout the entire lasing process.
- K. Terminate the saline/LR injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20cc of saline/LR in preparation for the next lasing sequence.
- L. Each subsequent laser train should be preceded by a bolus of saline/LR and performed with continuous saline/LR infusion as described in steps H-K.
- M. If contrast is used to assess treatment results during the course of a laser treatment, repeat steps D - G prior to reactivation of the laser system (before activating the laser as described in steps H - K).

**Note**

Depending on which approach is used, antegrade or contralateral, saline/LR can be administered through the sheath (antegrade approach) or laser catheter inner lumen (contralateral approach). When the contralateral approach is used, smaller diameter guidewires are suggested to allow adequate saline/LR infusion at the treatment site.

**12. Company Information**

The company's standard one-year product warranty and remedy are exclusive and expressly in lieu of all other warranties expressed or implied either in fact or by operation of law, statutory or otherwise, including warranties of merchant ability and fitness for use or for any particular purpose and of all other liabilities or obligations on the part of the company relating in any way to the CVX-300<sup>®</sup> Excimer Laser System, whether arising from personal injury, property damage or otherwise. The company neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System. Notwithstanding the generality of the foregoing, (a) the company shall have no liability whatsoever for special, consequential, incidental or punitive damages of any kind arising out of the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System, and (b) the company's liability shall in no event exceed the original purchase price of the CVX-300<sup>®</sup> Excimer Laser System.

***Spectranetics***

Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, Colorado 80907-5186  
USA

Telephone 719-633-8333

proposed

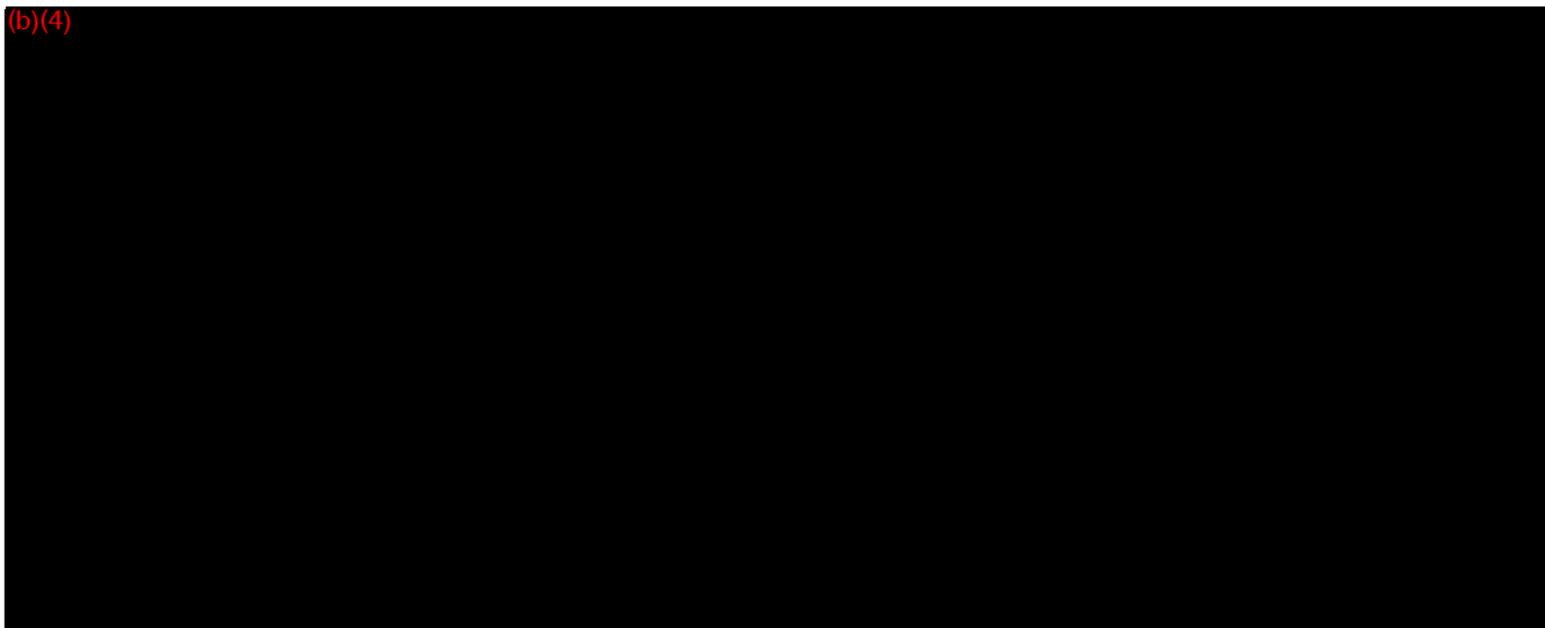
August, 2005

Spectranetics International BV  
Plesmanstraat 6  
3833 LA Leusden  
The Netherlands  
Telephone 31-33-434-7050

**Cavanaugh, Kenneth J**

---

**From:** Neil.Burris@spectranetics.com  
**Sent:** Tuesday, August 16, 2005 11:35 AM  
**To:** kjc@cdrh.fda.gov  
**Cc:** Kelly\_Elliott/Spectranetics/US@SPECTRANETICS.COM; Adrian.Elfe@spectranetics.com; Mike\_Ryan/notesadmin/US@spectranetics.com  
**Subject:** 2.5 mm Turbo CLiRpath Catheter K043465



Regards,

Neil

Neil Burris  
Clinical Data  
Spectranetics Corp.  
719 442 2456 direct  
1 800 633 0960 ext 456  
719 442 2481 fax

Do not use in combination with any other laser system.

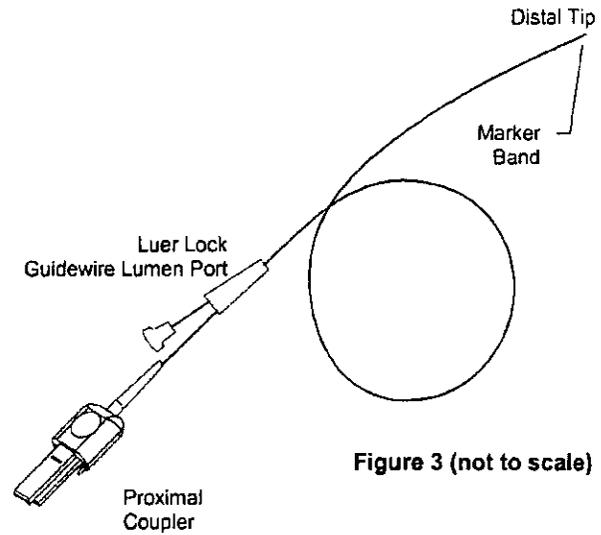
**Guidewire Compatibility**

See Catheter Specification Table in Section 1.

**11. Directions for Use**

Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the laser catheter from the tray while supporting the black laser connector, also known as the proximal end, proximal coupler, or proximal connector. Please note that the proximal end of the laser catheter connects only to the CVX-300®, and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the CVX-300® and position the laser catheter in the laser system extension pole. Calibrate the laser catheter following the instructions provided in the CVX-300® Operator's Manual (7030-0035 or 7030-0068).



**Figure 3 (not to scale)**

1. Use standard femoral puncture technique to insert a 5 Fr. to 9 Fr. (depending on the largest interventional device to be used during treatment) introducer sheath into the common femoral artery in antegrade or retrograde fashion for contralateral approaches. Heparinize intravenously using the PTA protocol for heparinization.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014", 0.016", 0.018", 0.025", or 0.035" guidewire to the peripheral occlusion via the introducer sheath or guiding catheter.
4. Size and choose the laser catheter appropriately:

**Table 11.1 Recommended Sizing**

Catheter Size	Proximal Vessel Diameter
0.9 mm	≥2.0 mm
1.4 mm	≥2.2 mm
1.7 mm	≥2.5 mm
2.0 mm	≥3.0 mm
2.3 mm	≥3.2 mm
2.5 mm	≥3.5 mm

5. *This step applies only to Extreme catheter models.* Inject 5-10cc of heparinized saline or Lactated Ringer's solution through the laser catheter to flush the guidewire lumen. Attach a rotating hemostatic valve to the guidewire port into the guidewire lumen (See Figure 3). Introduce the distal tip of the Spectranetics laser catheter over the selected guidewire. Under fluoroscopic control, guide the laser catheter to the lesion. The laser catheter's radiopaque band marker indicates its position relative to the lesion.

**Note:**  
 During use within the body, similar to any device used for vascular intervention, always monitor Laser Catheter movement and the radiopaque tip marker position with fluoroscopy. The movement and rate of advancement of the catheter distal tip should correspond directly with the rate of advancement being applied to the proximal shaft of the catheter.  
  
 If corresponding movement is not apparent, reassess the lesion morphology, the laser energy being applied and the status of support equipment prior to continued treatment.

6. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
7. Following confirmation of the laser catheter's position in contact with the target lesion and using normal saline or Lactated Ringer's solution:
  - a. Flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors,
  - b. Flush all residual contrast media from the lasing site and vascular structures adjacent to the lasing site, prior to activating the CVX-300® laser system.
  - c. Please refer to the Saline Infusion Protocol section of these Instructions for Use and perform saline flush and infusion per the instructions.
8. Depress the footswitch, activating the CVX-300®, and **slowly**, less than 1 mm per second, advance the laser catheter 2-3 mm into the total occlusion, allowing the laser energy to remove the desired material. Release the footswitch to deactivate the CVX-300®.

## EXCIMER LASER SALINE INFUSION PROTOCOL

### Note

Advancing the laser catheter through moderately calcified lesions may require more pulses of laser energy than fibrous atherosclerotic tissue.

9. When using Clirpath® Turbo models, the CVX-300® laser system will continuously deliver energy as long as the footswitch is depressed. The length of the laser train is controlled by the operator. It is generally recommended not to exceed 20 seconds of continuous lasing.
10. Advance the guidewire beyond the distal tip of the laser catheter further into the occlusion, a few millimeters, and reactivate the laser as described in Step 8 above.
11. Continue in this step-by-step manner where the guidewire and then the laser catheter are advanced and activated (mm by mm) until the catheter reaches the last 3-5 mm of the occlusion.
12. Cross the last 3-5 mm of the occlusion and enter the patent distal vessel with the guidewire first, followed by the activated laser catheter over the wire.
13. Leaving the guidewire in position, pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.
14. Additional laser passes may be performed over the wire to achieve greater debulking of the lesion.

### Note

If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter outer surface, inner lumen, and tip with heparinized saline to prevent blood from sticking. Blood remaining on the laser catheter may diminish the efficiency of the laser catheter.

If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the CVX-300®. The fluence and repetition rates can be increased in order to advance. To avoid the potential of heat build-up, the catheter must be advanced while lasing.

15. There is no need to remove the laser catheter from the patient in order to increase or decrease either the fluence or pulse repetition rate; as the laser catheter was previously calibrated. Refer to the CVX-300® Excimer Laser System Operator's Manual, 7030-0035 or 7030-0068.

### Caution

All patients should be monitored for blood pressure and heart rate during the procedure.

16. Following laser recanalization, perform follow up angiography and balloon angioplasty if needed. Stenting may be performed as required, in instances of acute recoil, major perforation, etc.
17. Recommended pharmacology follow up to be prescribed by the physician.

### Note

This technique requires two operators. It is recommended that the primary physician operator advance the laser catheter and operate the laser system foot pedal. A scrub assistant should manage the saline infusion control syringe and (if appropriate) depress the fluoroscopy pedal.

- A. Before the laser procedure, warm a 500cc bag of 0.9% normal saline (NaCl), or Lactated Ringer's (LR) solution, to 37°C. It is not necessary to add heparin or potassium to the saline/LR solution. Connect the bag of warmed saline/LR to a sterile intravenous line and terminate the line at a port on a triple manifold.
- B. If applicable, cannulate the ostium of the artery with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter not have side holes.
- C. Under fluoroscopic guidance, advance the laser catheter into contact with the lesion. If necessary, inject contrast to help position the tip of the laser catheter. If contrast appears to have become entrapped between the laser catheter tip and the lesion, the laser catheter may be retracted slightly (1-2mm) to allow antegrade flow and contrast removal while flushing the system with saline/LR. **However, before lasing, ensure that the laser catheter tip is in contact with the lesion.**
- D. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline/LR through the manifold into the control syringe.
- E. Remove the original control syringe from the manifold and replace it with a fresh 20cc luer-lock control syringe. This new 20cc control syringe should be primed with saline/LR prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20cc control syringes.)
- F. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and introducer sheath or guide catheter, with at least 20-30cc of saline/LR (several syringes of saline/LR). When this initial flushing is completed, refill the 20cc control syringe with saline/LR.
- G. Under fluoroscopy, confirm that the tip of the laser catheter is in contact with the lesion (advance the laser catheter if necessary), but do not inject contrast.
- H. When the primary operator indicates that he/she is ready to activate the laser system, the scrub assistant should turn the manifold stopcock off to pressure and inject 10cc of saline/LR as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
- I. After the injection of the initial 10cc bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3cc/second. This portion of the saline/LR infusion is to displace and/or dilute the antegrade blood flow entering

the laser ablation field. At the instant the scrub assistant slows down the injection rate, the primary operator should activate the laser system by depressing the foot pedal and begin a lasing sequence.

- J. The length of the laser train is controlled by the operator. It is generally recommended not to exceed 20 seconds of continuous lasing. Saline/LR must be infused throughout the entire lasing process.
- K. Terminate the saline/LR injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20cc of saline/LR in preparation for the next lasing sequence.
- L. Each subsequent laser train should be preceded by a bolus of saline/LR and performed with continuous saline/LR infusion as described in steps H-K.
- M. If contrast is used to assess treatment results during the course of a laser treatment, repeat steps D - G prior to reactivation of the laser system (before activating the laser as described in steps H - K).

**Note**

Depending on which approach is used, antegrade or contralateral, saline/LR can be administered through the sheath (antegrade approach) or laser catheter inner lumen (contralateral approach). When the contralateral approach is used, smaller diameter guidewires are suggested to allow adequate saline/LR infusion at the treatment site.

**12. Company Information**

The company's standard one-year product warranty and remedy are exclusive and expressly in lieu of all other warranties expressed or implied either in fact or by operation of law, statutory or otherwise, including warranties of merchant ability and fitness for use or for any particular purpose and of all other liabilities or obligations on the part of the company relating in any way to the CVX-300<sup>®</sup> Excimer Laser System, whether arising from personal injury, property damage or otherwise. The company neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System. Notwithstanding the generality of the foregoing, (a) the company shall have no liability whatsoever for special, consequential, incidental or punitive damages of any kind arising out of the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System, and (b) the company's liability shall in no event exceed the original purchase price of the CVX-300<sup>®</sup> Excimer Laser System.



Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, Colorado 80907-5186  
USA

Telephone 719-633-8333

Spectranetics International BV  
Plesmanstraat 6  
3833 LA Leusden  
The Netherlands  
Telephone 31-33-434-7050

proposed

August, 2005

From: Reviewer(s) - Name(s) Ken Cavanaugh

Subject: 510(k) Number 1043465/S1

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):  
 No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

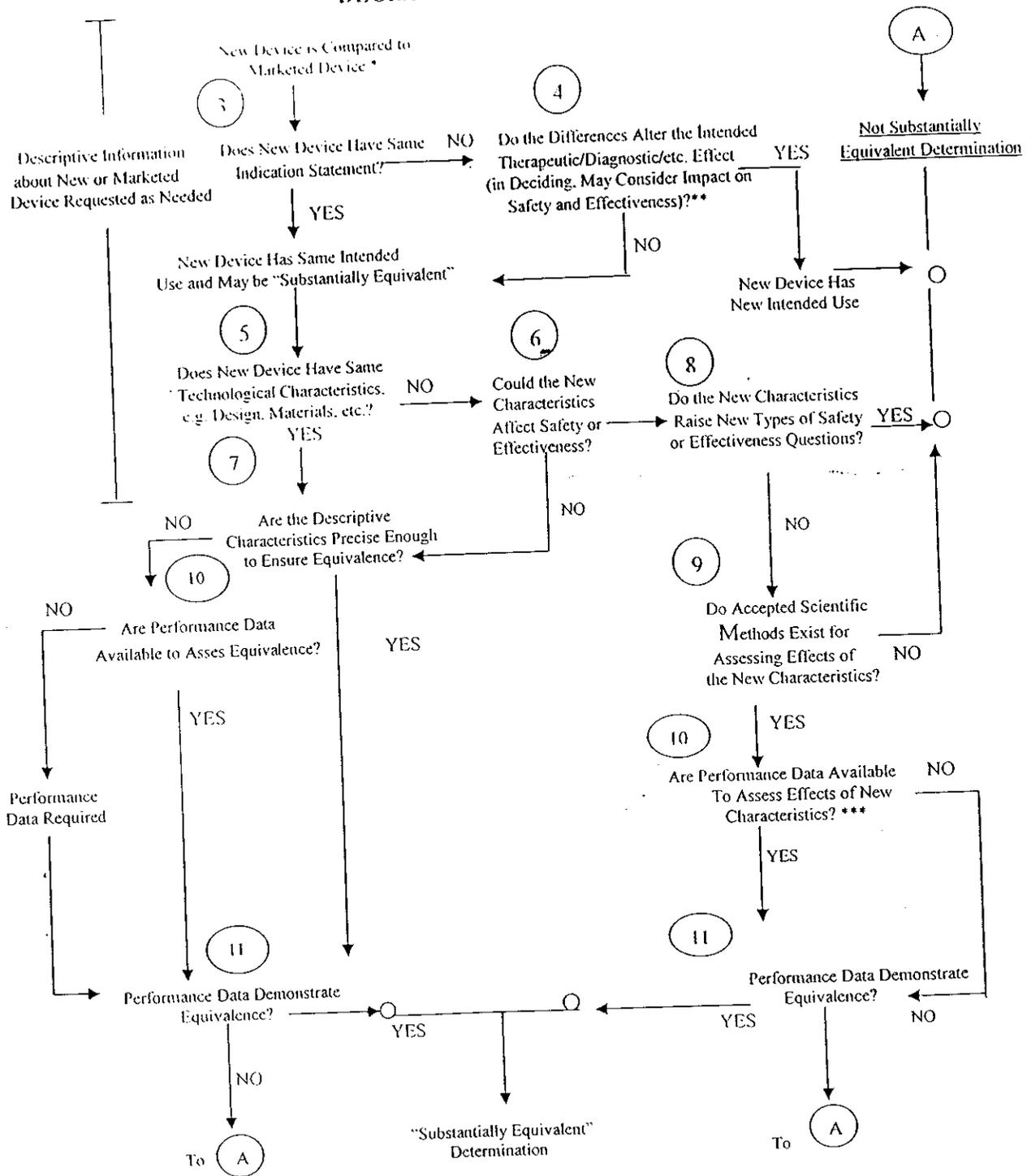
Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

MCW - Class II

Review: [Signature] P0DB 8/2/05  
(Branch Chief) (Branch Code) (Date)

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

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



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

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

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

YES NO

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

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

1. Intended Use:

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

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION



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

**Date:** July 29, 2005  
**From:** Kenneth J. Cavanaugh, Jr., Ph.D., Biomedical Engineer  
FDA/CDRH/ODE/DCD/PVDB  
**510(k) Number:** K043465 S001

**Device Name:** 2.5 mm Turbo Excimer Laser Catheter (Model 225-011)  
**Product Code:** 74 MCW – Catheter, Peripheral, Atherectomy **CFR Code:** 870.5150

**Manufacturer:** Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, CO 80907-5186

**Contact:** Neil Burris, Clinical Data Services  
Phone: (719) 442-2456 Fax: (719) 442-2481  
Email: [neil.burris@spectranetics.com](mailto:neil.burris@spectranetics.com)

or

Adrian Elfe  
Phone: (719) 442-2425  
Email: [adrianelfe@spectranetics.com](mailto:adrianelfe@spectranetics.com)

**Predicate Devices:** K040067 – Spectranetics CLiRpath Excimer Laser Catheters

**I. Introduction**

This premarket notification submission is for a new device, the 2.5 mm Turbo Excimer Laser Catheter, which would be a Class II device upon clearance. The manufacturer wishes to add this new catheter model to their existing CLiRpath Excimer Laser Catheter line. The currently marketed CLiRpath catheters were cleared under premarket notification K040067 and will serve as the predicate devices for the new Turbo catheter model. The new device has the same indications as the previously cleared catheters but incorporates several design changes, most notably the addition of a lubricious coating, a greater number of optic fibers, and continuous “on” capability.

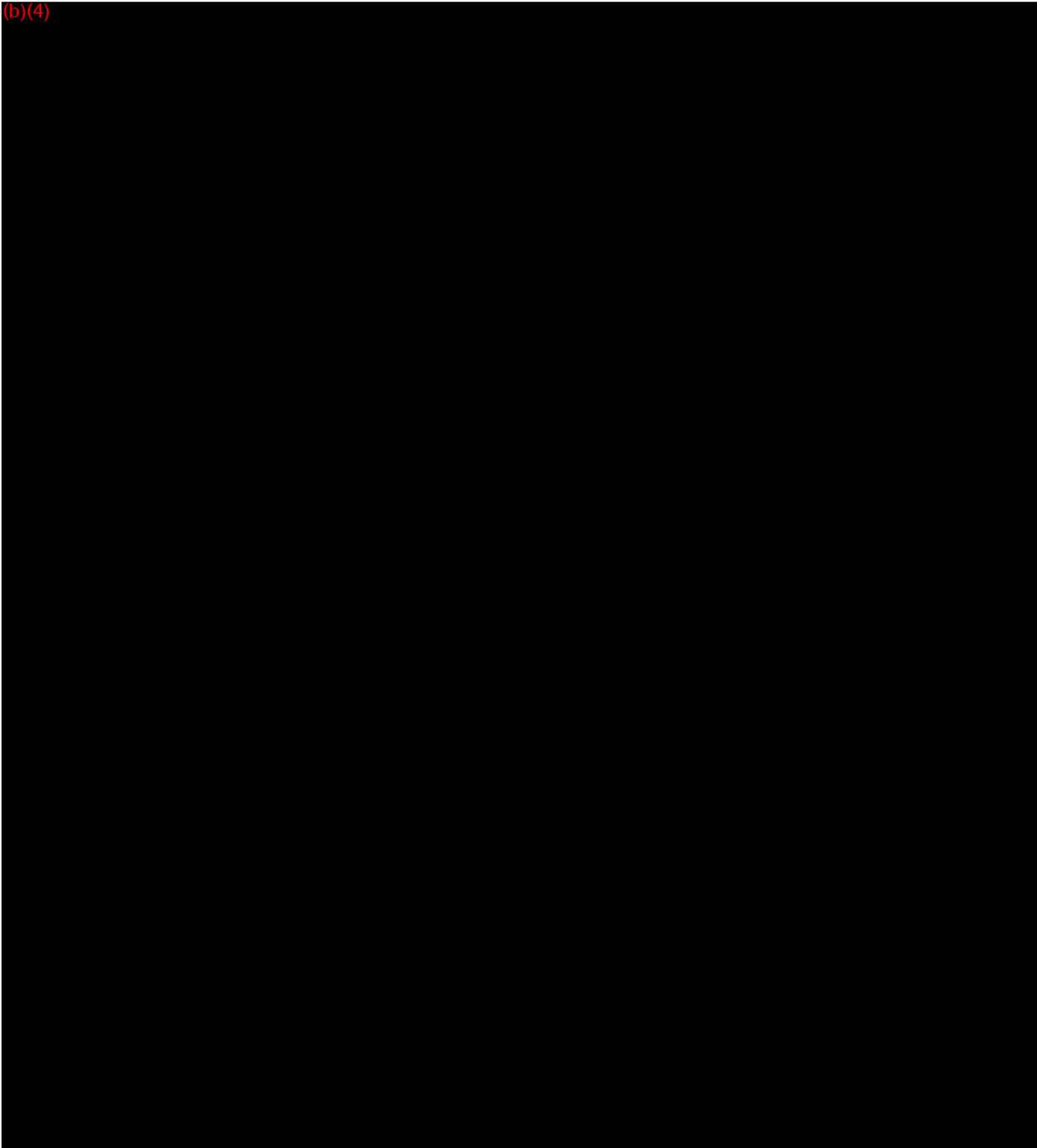
The original 510(k) submission was put on hold on January 31, 2005, pending the submission of additional information. With this supplement, the applicant has attempted to address each of FDA’s previously identified deficiencies.

**II. Review of Submission**

Each of the deficiencies identified in FDA’s 1/31/05 letter is presented below, followed by a review and summary of the applicant’s response.

Animal Studies

(b)(4)





(b)(4)



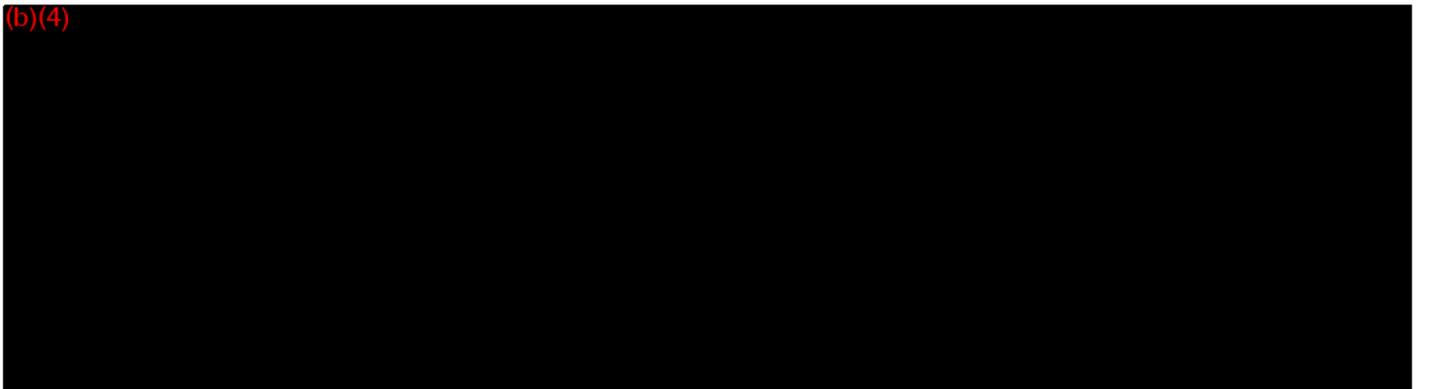
**Acceptable response.**

(b)(4)

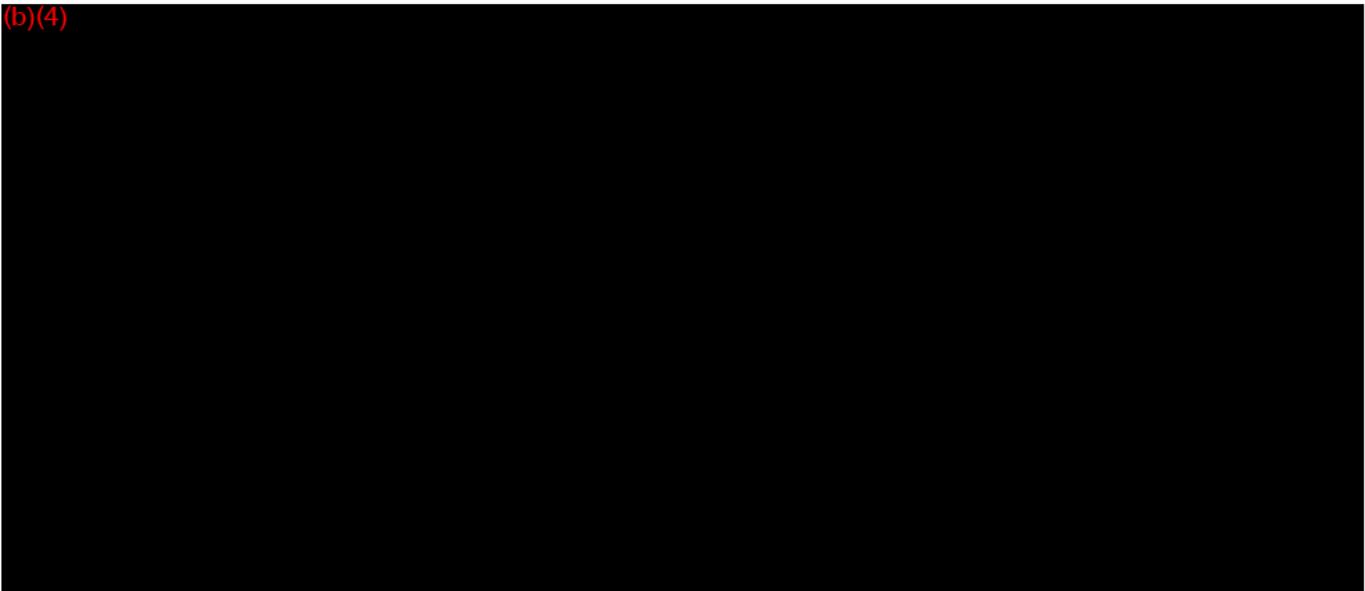


**Acceptable response.**

(b)(4)



(b)(4)



**Deficiency:**



(b)  
(4)

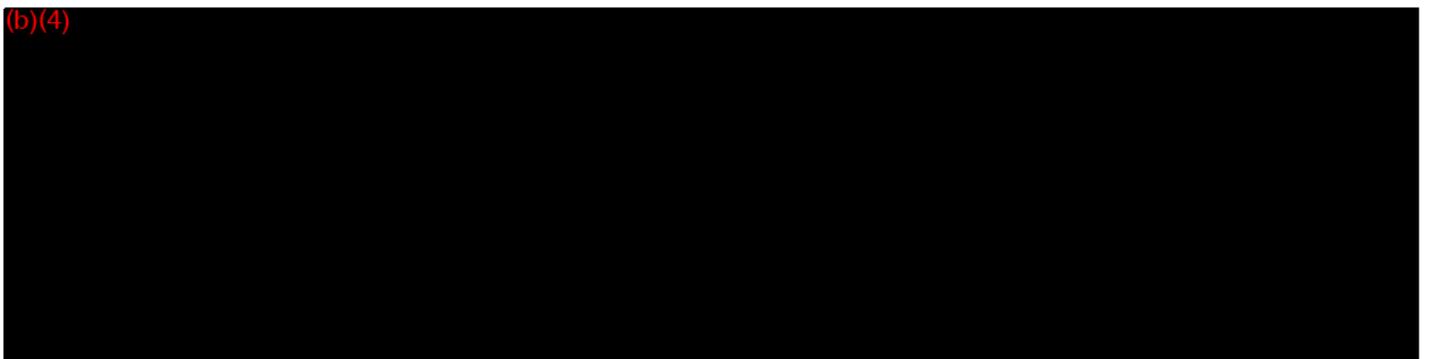
rationale

(b)(4)



**Adequate response.**

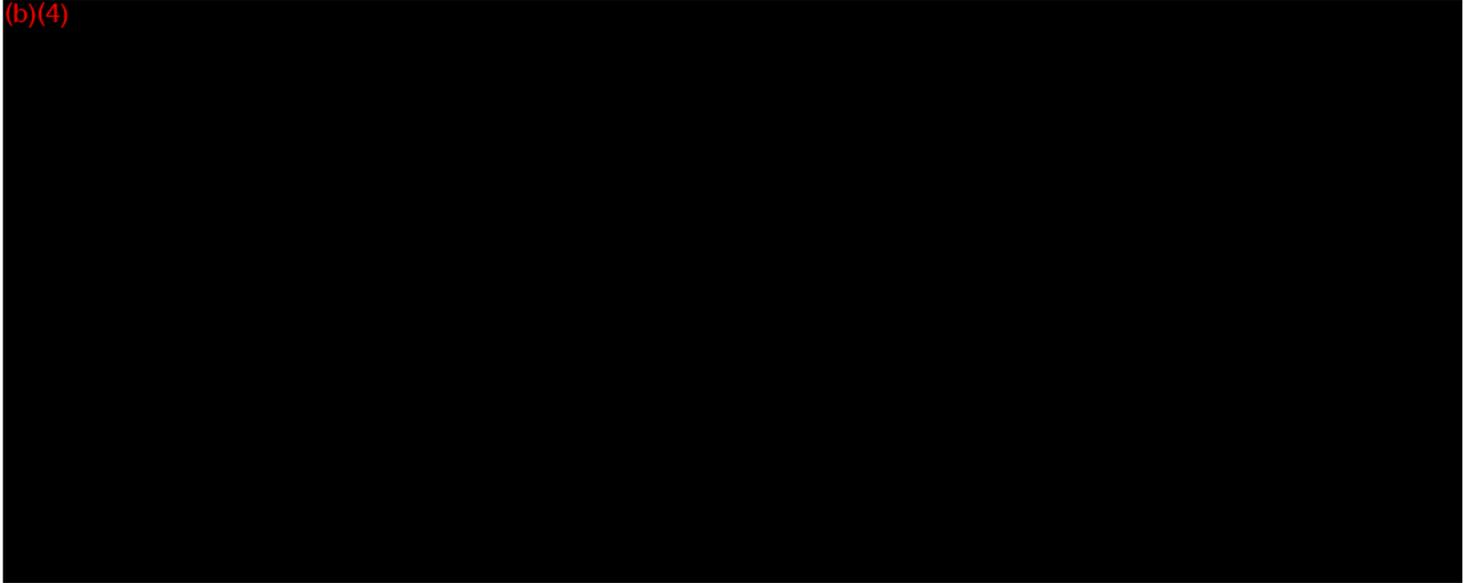
(b)(4)



**Adequate response.**

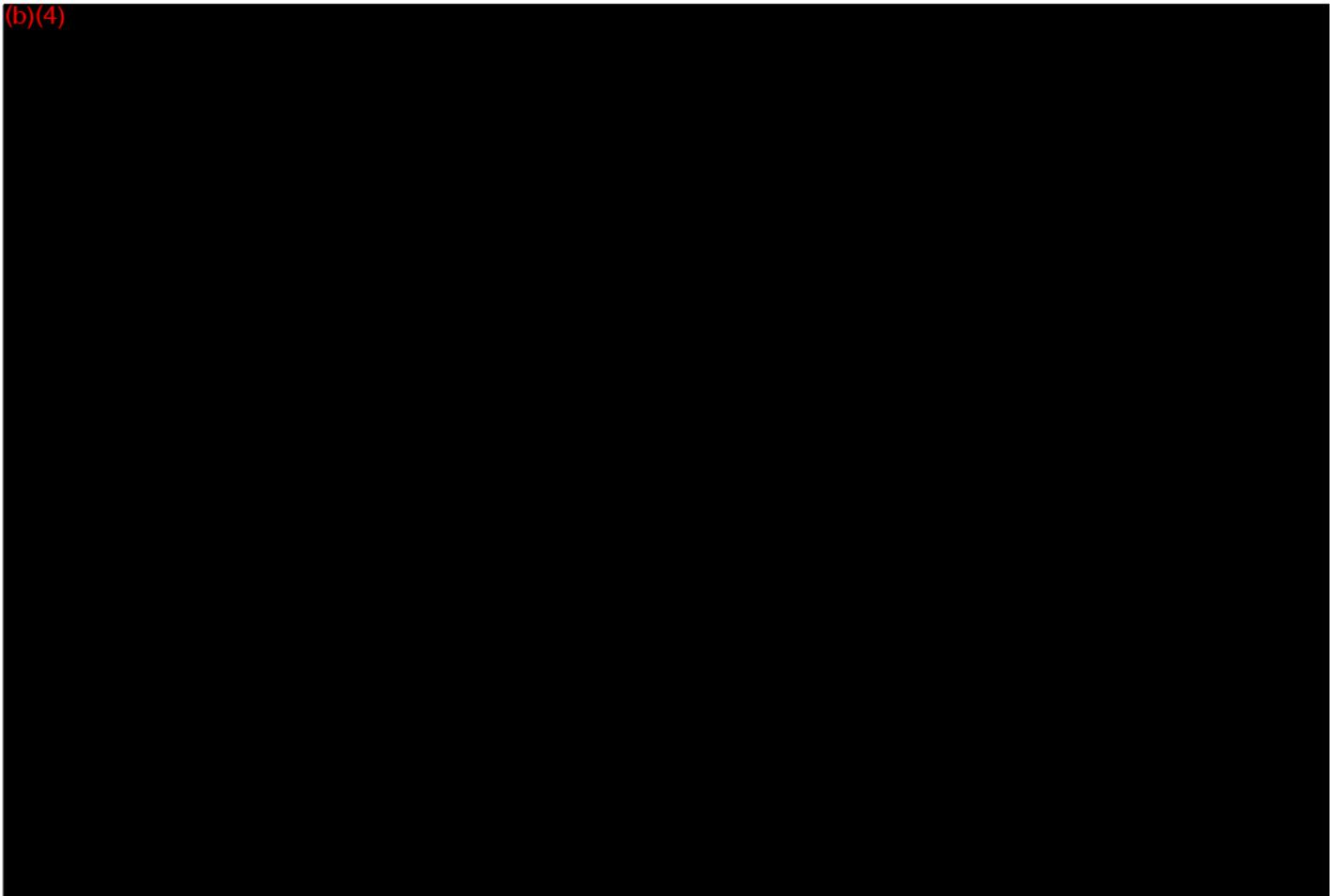
Biocompatibility

(b)(4)



**Acceptable response.**

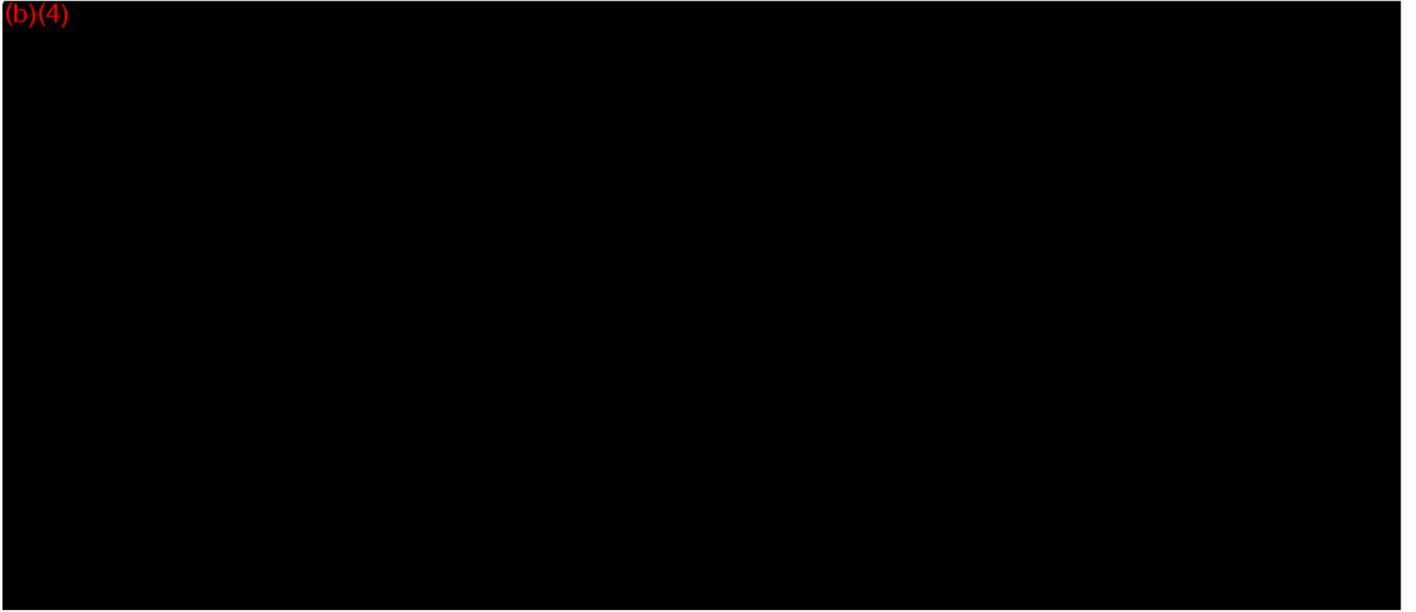
(b)(4)



**Acceptable response.**

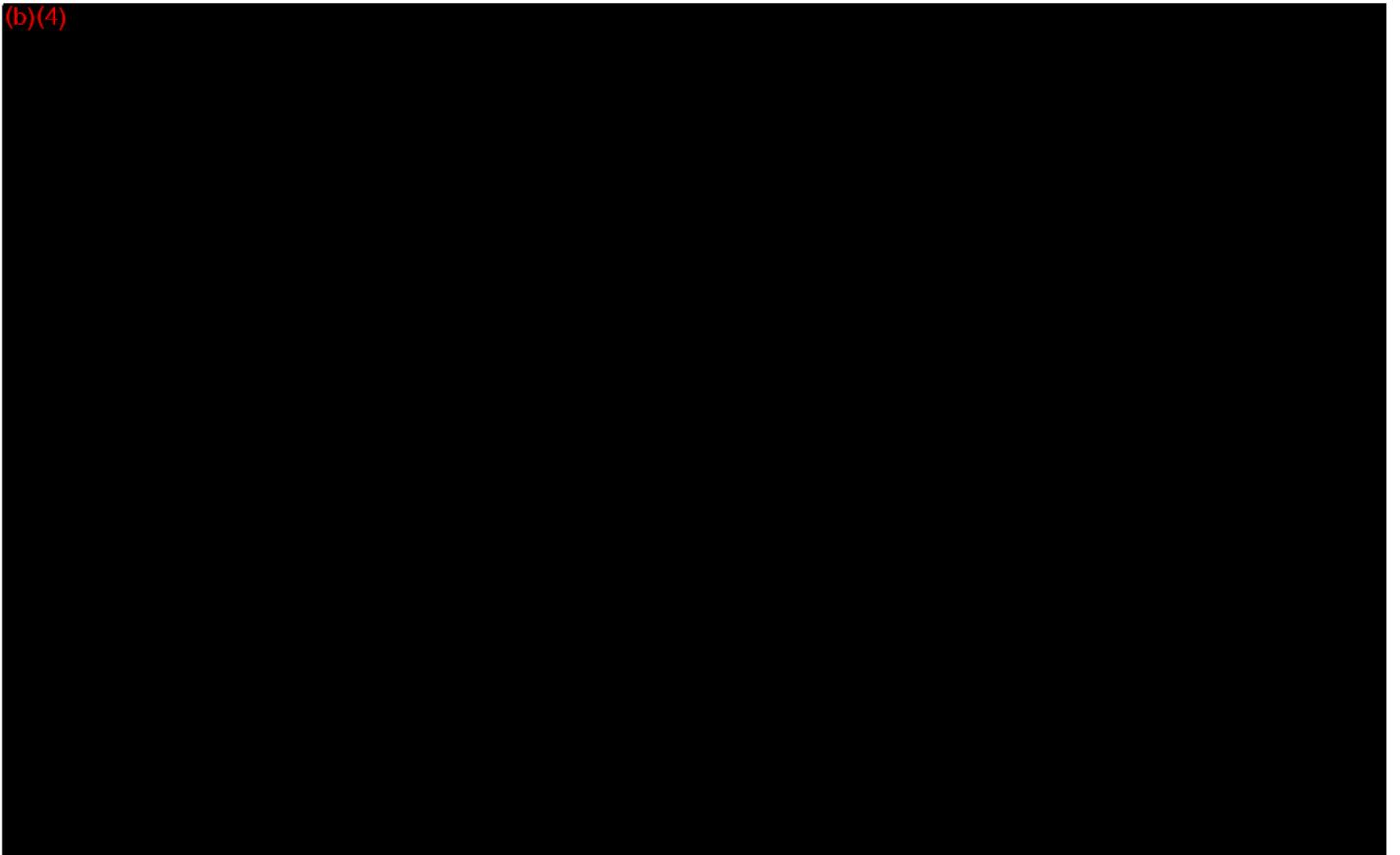
*Sterilization, Packaging, and Shelf-Life*

(b)(4)



**Acceptable response.**

(b)(4)

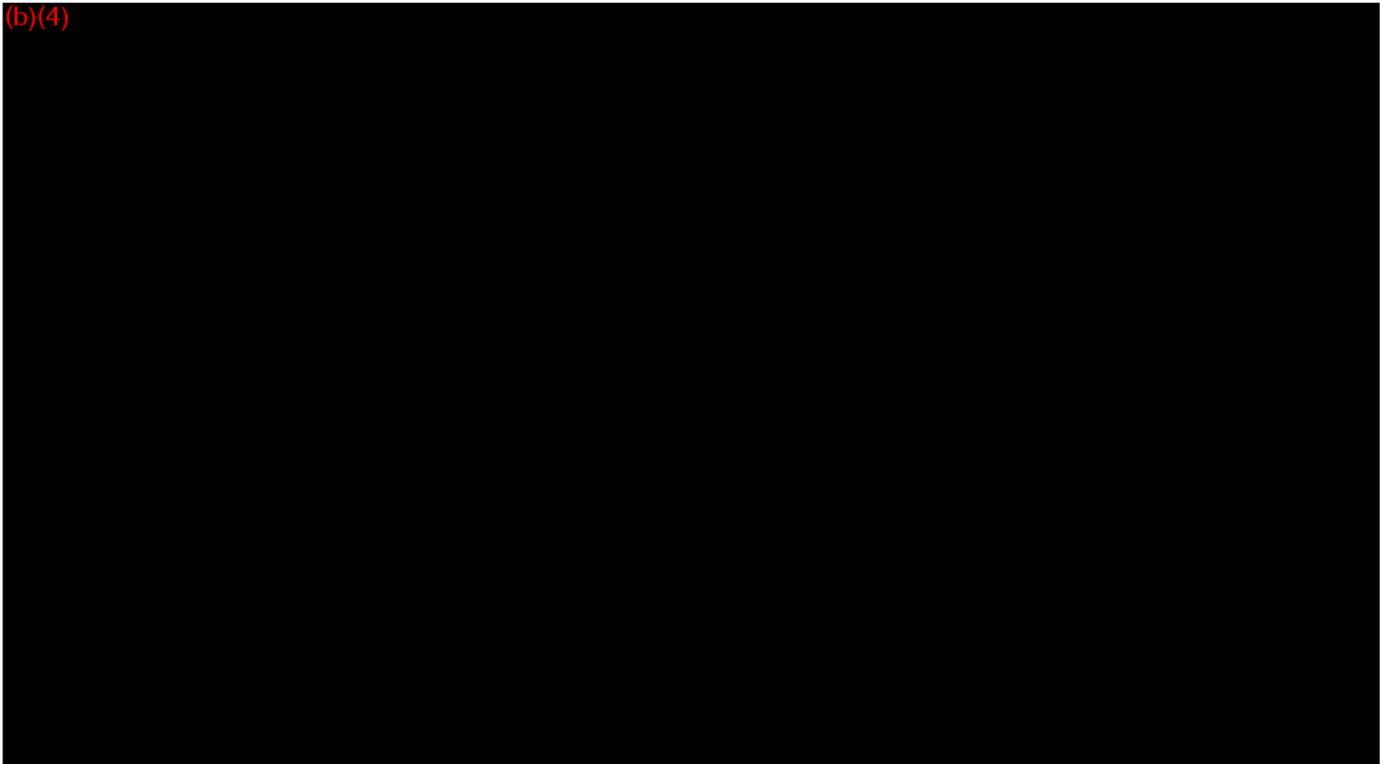


(b)(4)



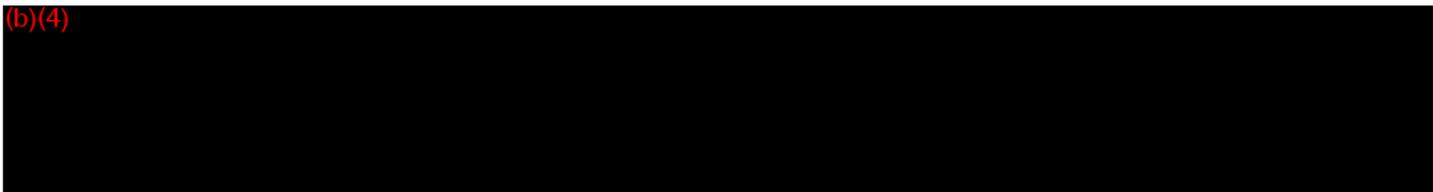
**Deficiency:** P [redacted] s (b)(4) [redacted] e [redacted]  
[redacted]

(b)(4)



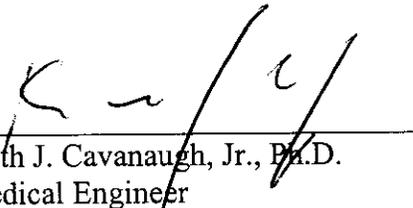
*Labeling / IFU*

(b)(4)



**Acceptable response.**

**Reviewer Recommendation: Additional Information - AI**



Kenneth J. Cavanaugh, Jr., Ph.D.  
Biomedical Engineer  
Peripheral Vascular Devices Branch



Chief  
Peripheral Vascular Devices Branch

Date: July 29, 2005

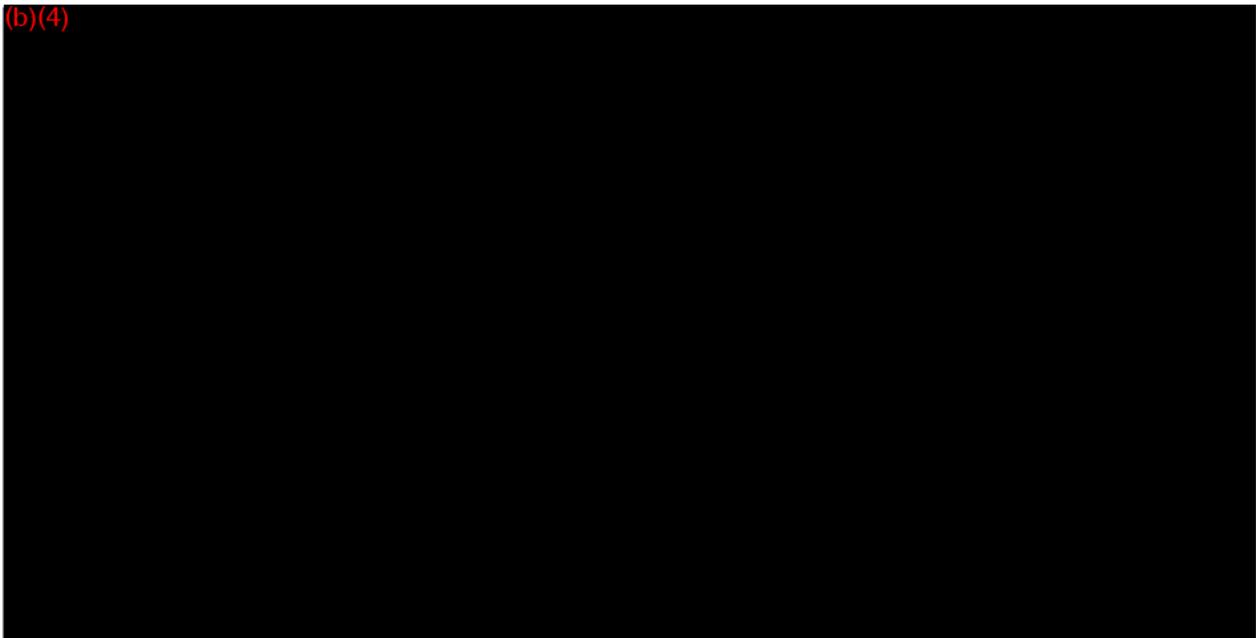
To: Kenneth Cavanaugh  
Biomedical Engineer  
PVDB/DCD/ODE (HFZ-450)

From: William K. Riemenschneider, MS  
Biologist  
CSPB/DCD/ODE (HFZ-450)

Subject: Spectranetics 2.5 Turbo CLiRpath Excimer Laser Catheter Ablation Device  
(K043465-S01).

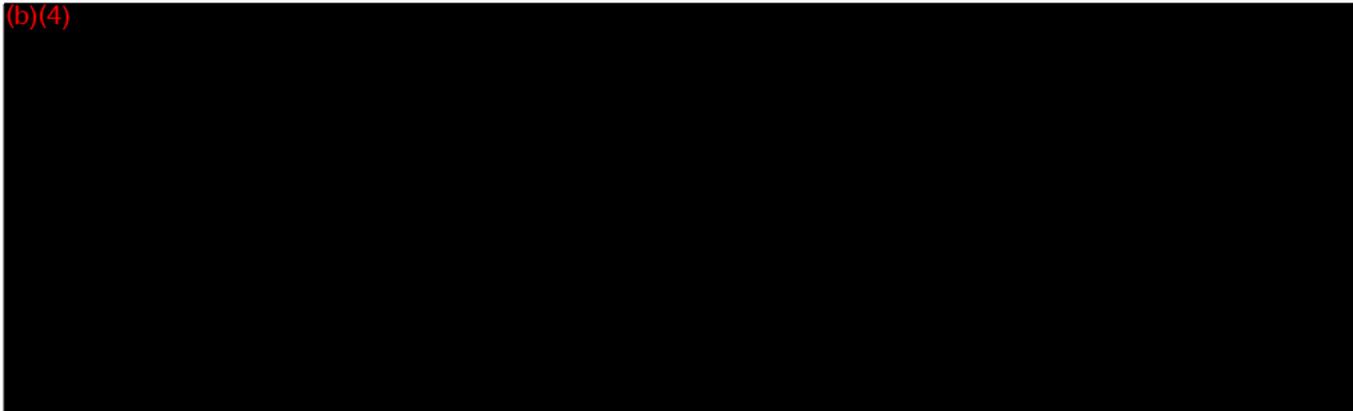
Original FDA questions in italics:

(b)(4)



**Experimental Design:**

(b)(4)



(b)(4)

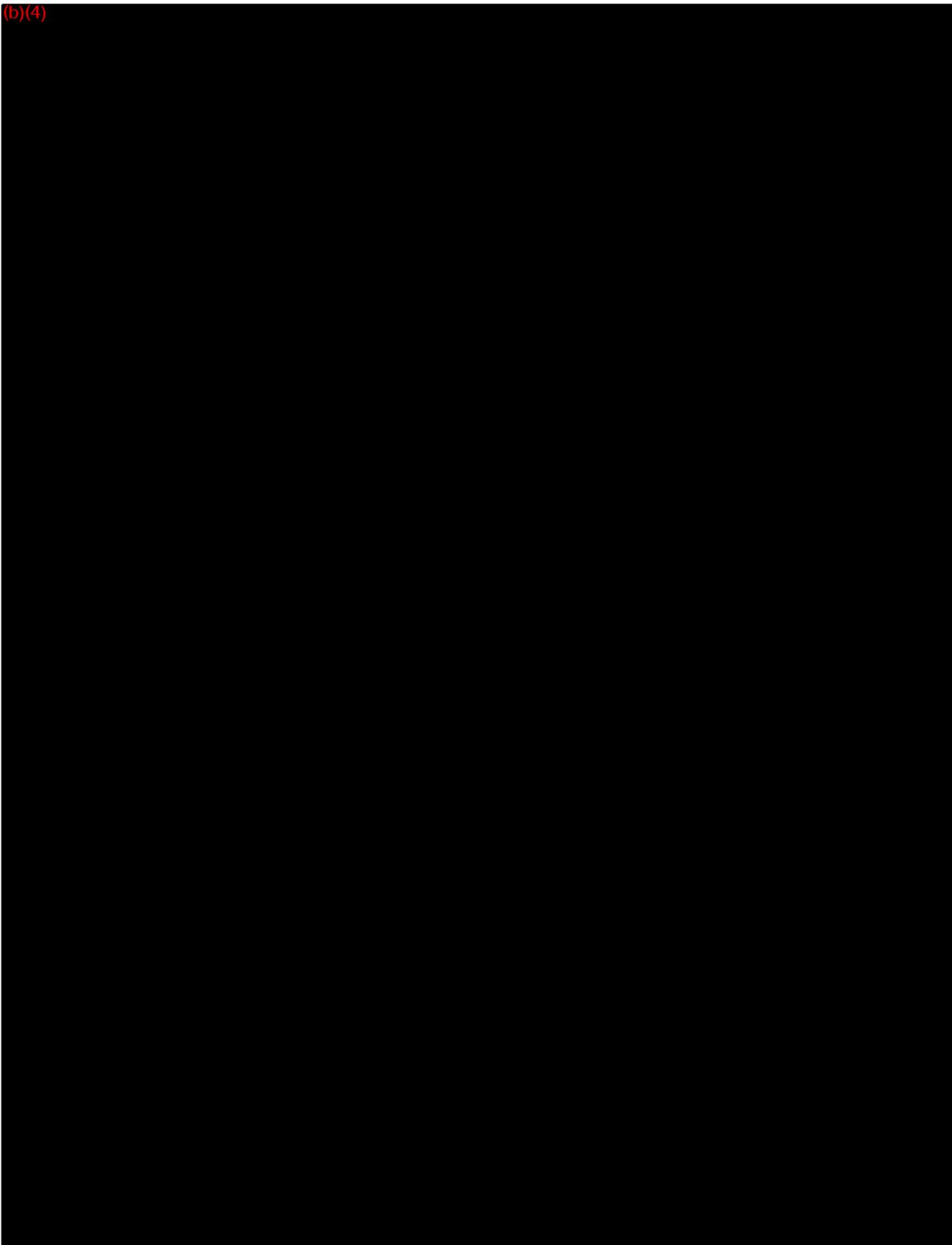


**Results:**

(b)(4)



(b)(4)

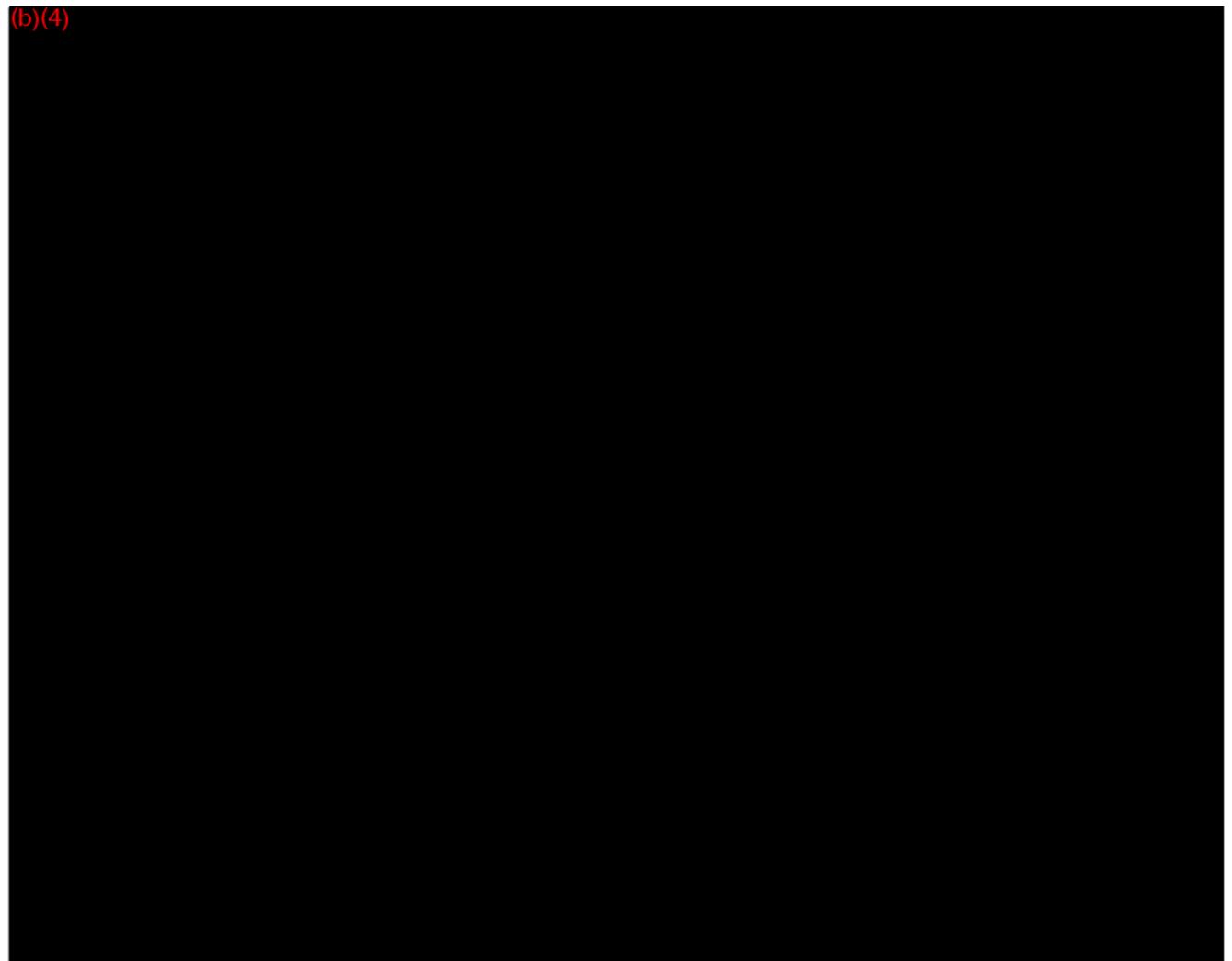


(b)(4)

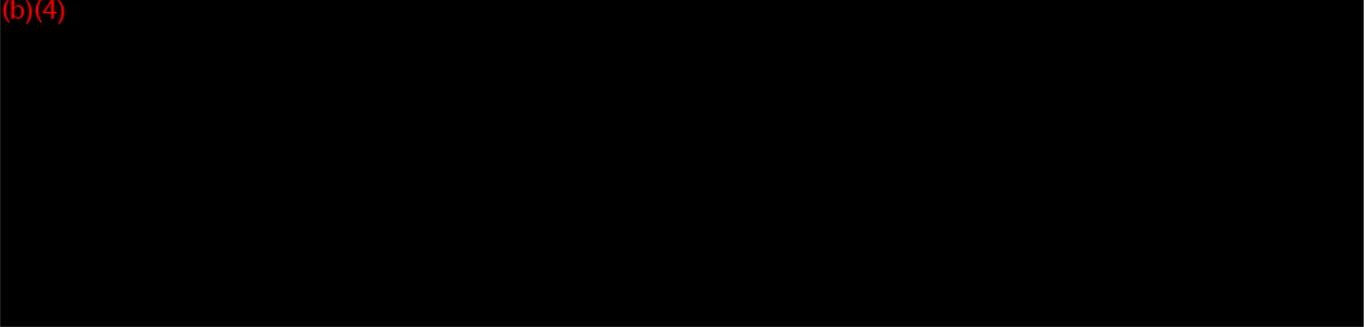


**Reviewer Recommendation:**

(b)(4)



(b)(4)

















































































































































































# Memo

*dc 12/2/04*  
To: TA# 11053  
From: Rob Carver  
Date: 12/2/2004  
Subject: Changes to pin code to implement 45f1

---

The changes and justifications are as follows:

Change	From	From	Justification
(b) (4)			

To: Mary de Sousa, Jeff Bird, Paul Hollendorfer, Kevin Taylor  
 Ce: Neil Burris, Rob Carver, Mary de Sousa, Jamie Fearing, Tamara Fischer, Andy Lerohl, Tony Morris, James Nye, Shane Pitzer, Scott Tedder  
 From: Wade Bowe  
 Date: 10/05/04  
 Subject: 2.5 Turbo Max Fluence Design Review 10/04/04

Attendees: Jeff Bird, Wade Bowe, Rob Carver, Mary de Sousa, Paul Hollendorfer, Kevin Taylor  
 Action Items:

(b)(4) Product Specs  
 [Redacted]

Discussion:  
 [Redacted] (b)(4)

Coupling Efficiency:  
 [Redacted] (b)(4) Product

Regulated Energy:  
 [Redacted] (b)(4)

Increased Energy vs the 2.5 Extreme II:  
 [Redacted] but [Redacted] (b)(4)

Analysis:  
 (b)(4) Product Specs  
 [Redacted]

Name	Signature	Title	Date
Jeff Bird		Director, Field Service	
Wade Bowe		R&D Group Leader	
Rob Carver		R&D Engineer	
Mary de Sousa		Marketing Manager, CLiRpath	
Paul Hollendorfer		Manager, Manufacturing Engineering	
Kevin Taylor		Director, R&D	

**Spectranetics**

*we get your blood flowing™*

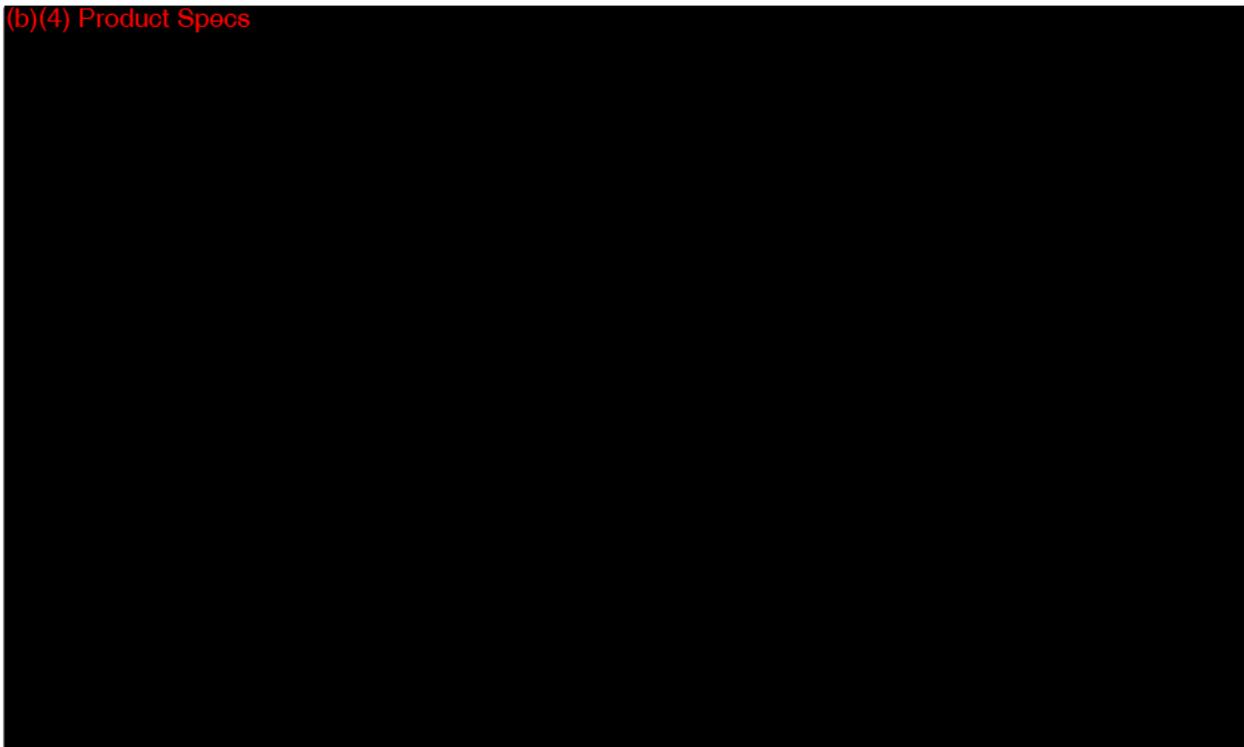
# Memo

**To:** TA 11053  
**From:** James Nye  
**Date:** 01/03/05  
**Re:** Reissue #1 Changes

*James Nye 1-3-05*

The following documents require a name change from Inner or Dugl Catheter to 2.5 Turbo:

(b)(4) Product Specs



James Nye  
Manufacturing Engineer  
Spectranetics Corporation

*R+D [Signature] 1-4-05*

*[Signature] 1/5/05*

● Page 1

TA # 11053  
Expires 4/30/05

PAGE 68 OF 73

























# Memo

To: TA# 11058  
From: Rob Carver  
Date: 3/23/2005  
Subject: Changes to P/N 3650-1214

---

The changes and justifications are as follows:

Change	From	From	Justification
(b)(4) Product Specs			

TA 11058  
Jr 3-29-05  
Rbc 3-23-05  
M 3/23/05

TA # 11053  
Expires 7/24/05

PAGE 11 OF 81

235

From: Reviewer(s) - Name(s) Ken Cavanaugh  
Subject: 510(k) Number K093465

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- |   |   |  |
|---|---|--|
| Is this device subject to Section 522 Postmarket Surveillance?    | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation?                | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Is this a prescription device?                                    | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO            |
| Was this 510(k) reviewed by a Third Party?                        | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Special 510(k)?   | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO    Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):  
 No Confidentiality     Confidentiality for 90 days     Continued Confidentiality exceeding 90 days

Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

MCW - Class II

Review: QJML PDOB 1/31/05  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_ (Date)  
(Division Director)



## *Internal Administrative Form*

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

**SCREENING CHECKLIST  
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: \_\_\_\_\_

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

**Section 1: Required Elements for All Types of 510(k) submissions:**

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

\* - May not be applicable for Special 510(k)s.

\*\* - Required for Class III devices, only.

\*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

**Section 2: Required Elements for a SPECIAL 510(k) submission:**

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

**Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:**

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and any additional information requested by the reviewer in order to determine substantial equivalence.</u>		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- \* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):**

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

*Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

Passed Screening \_\_\_\_ Yes \_\_\_\_ No

Reviewer: \_\_\_\_\_

Concurrence by Review Branch: \_\_\_\_\_

Date: \_\_\_\_\_

The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

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

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

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

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

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION



---

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

**Date:** January 26, 2005  
**From:** Kenneth J. Cavanaugh, Jr., Ph.D., Biomedical Engineer  
FDA/CDRH/ODE/DCD/PVDB  
**510(k) Number:** K043465

**Device Name:** 2.5 mm Turbo Excimer Laser Catheter (Model 225-011)  
**Product Code:** 74 MCW – Catheter, Peripheral, Atherectomy      **CFR Code:** 870.5150

**Manufacturer:** Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, CO 80907-5186

**Contact:** Neil Burris, Clinical Data Services  
Phone: (719) 442-2456      Fax: (719) 442-2481  
Email: [neil.burris@spectranetics.com](mailto:neil.burris@spectranetics.com)

or

Adrian Elfe  
Phone: (719) 442-2425  
Email: [adrianelfe@spectranetics.com](mailto:adrianelfe@spectranetics.com)

**Predicate Devices:** K040067 – Spectranetics CLiRpath Excimer Laser Catheters

---

**I. Introduction:**

This premarket notification submission is for a new device, the 2.5 mm Turbo Excimer Laser Catheter, which would be a Class II device upon clearance. The manufacturer wishes to add this new catheter model to their existing CLiRpath Excimer Laser Catheter line. The currently marketed CLiRpath catheters were cleared under premarket notification K040067 and will serve as the predicate devices for the new Turbo catheter model. The new device has the same indications as the previously cleared catheters but incorporates several design changes, most notably the addition of a lubricious coating, a greater number of optic fibers, and continuous “on” capability.

**II. Device Description:**

**A. Indications for Use**

The Spectranetics 2.5 mm Turbo Excimer Laser Catheter is indicated for use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions cannot be crossed with standard guide wires.

**B. 510(k) Summary:**

	YES	NO
Is the device life-supporting or life sustaining?	_____	X _____
Is the device implanted (short-term or long-term)?	_____	X _____
Is the device sterile?	X _____	_____
Is the device single use?	X _____	_____
Is the device home use?	_____	X _____
Is the device for prescription use?	X _____	_____
Does the device contain a drug or biological product?	_____	X _____
Is the device a kit?	_____	X _____
Is the device electrically operated?	X _____	_____
Does the device use software?	_____	X _____

The 2.5 mm Turbo Excimer Laser Catheter consists of a bundle of optical fibers encased within medical-grade tubing, with a working length of approximately 110 cm. It is designed to be connected to the Spectranetics CVX300 Excimer Laser (previously approved under PMA P910001) via an optical port located at the proximal end of the catheter. The optical fibers of the catheter conduct ultraviolet excimer laser light at a wavelength of 308 nm to the catheter tip. With the aid of a guidewire, the physician directs this laser energy to an occlusive lesion in the lower peripheral vasculature. This energy debulks the lesion material, thus opening the vessel and allowing passage of other interventional devices.

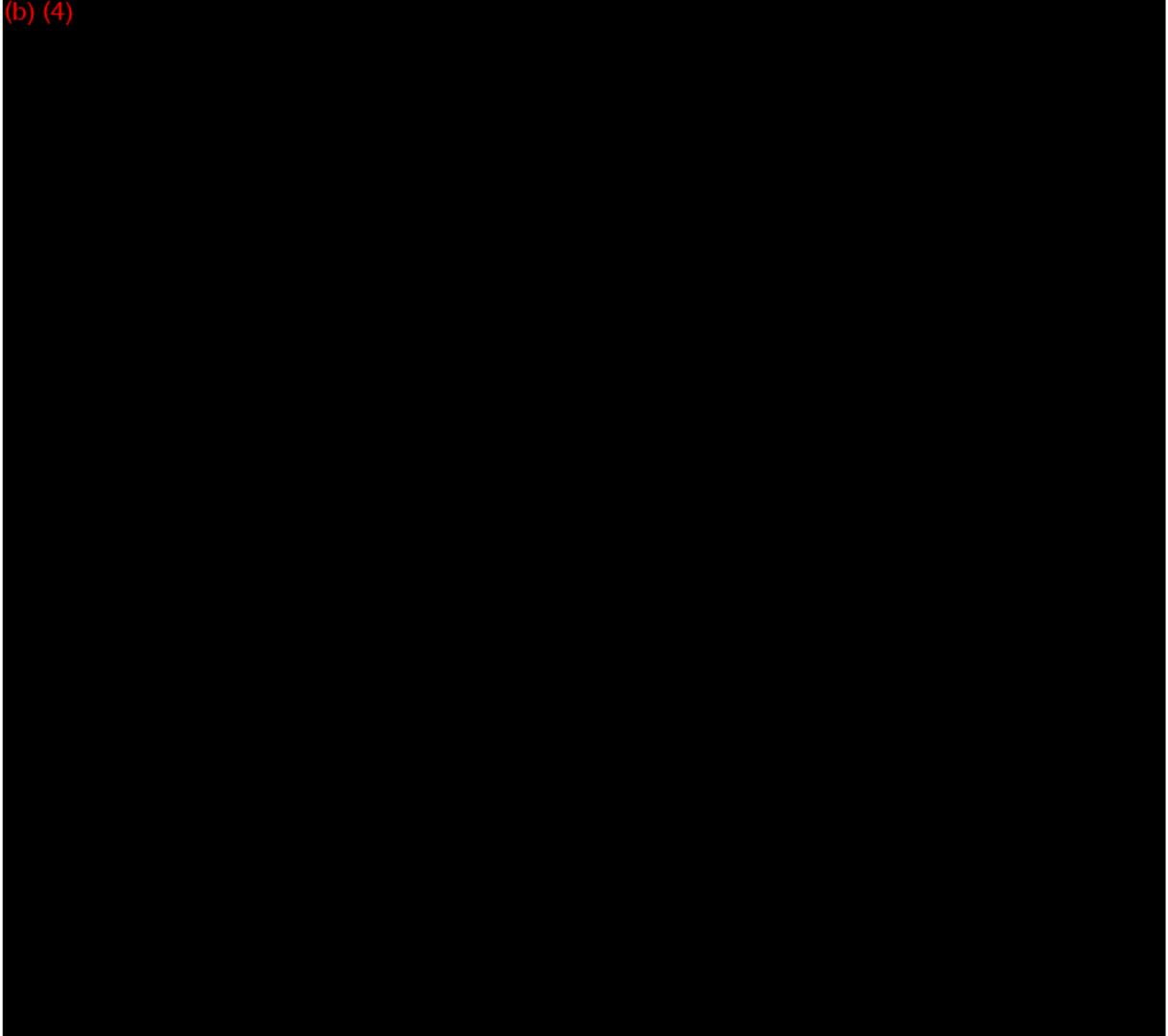
Using the Turbo laser catheter, the physician may employ a step-by-step technique to cross the lesion. This technique does not require the guide wire to cross the lesion prior to catheter advancement. The guidewire is advanced to the target lesion and is then used to facilitate placement of the catheter tip against the lesion. The laser energy is briefly activated, allowing the catheter to advance a few millimeters. The guidewire is then advanced a few millimeters beyond the catheter tip to probe for a path through the remaining occlusion length. If one cannot be found, the catheter is advanced to the end of the guidewire, and the laser is activated again. These steps are repeated until the physician is able to cross the entire lesion. The ablated lesion material is removed from the vasculature via the patient's reticuloendothelial system. Torque is delivered to the catheter via an external torque control handle. The catheter shaft possesses radiopaque markers to assist with visualization.

Upon clearance, the Turbo catheter will be Model 225-011 of the currently marketed CLiRpath excimer laser catheter line. In addition to several minor changes in materials and dimensions, there are several important differences between the Turbo catheter and the other CLiRpath laser catheters. The working length of the Turbo laser catheter is coated with a hydrophilic substance designed to increase lubricity. The catheter also possesses an increased number of optical fibers (128, compared to 96 for the other CLiRpath catheters). However, the operational energy remains the same for both catheter models (50 mJ/mm<sup>2</sup> at 40 Hz). Finally, the Turbo catheter is designed so that the laser can be operated continuously. The prior CLiRpath models required 5 seconds of laser down-time for every 10 seconds of operation.

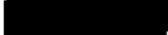
### III. Testing

#### A. Materials/Biocompatibility Testing

(b) (4)



*Deficiency:*







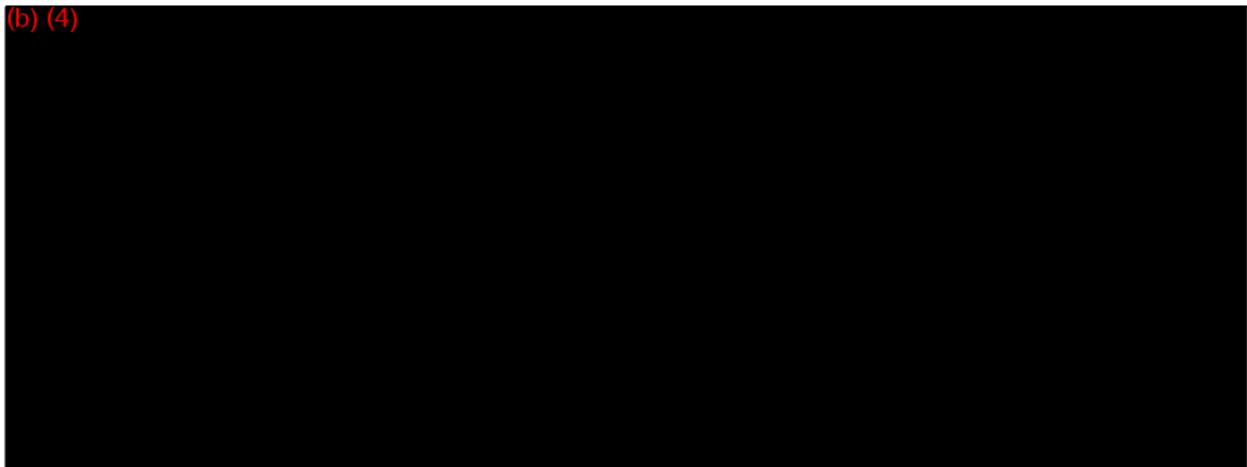


(b)

)

(4)

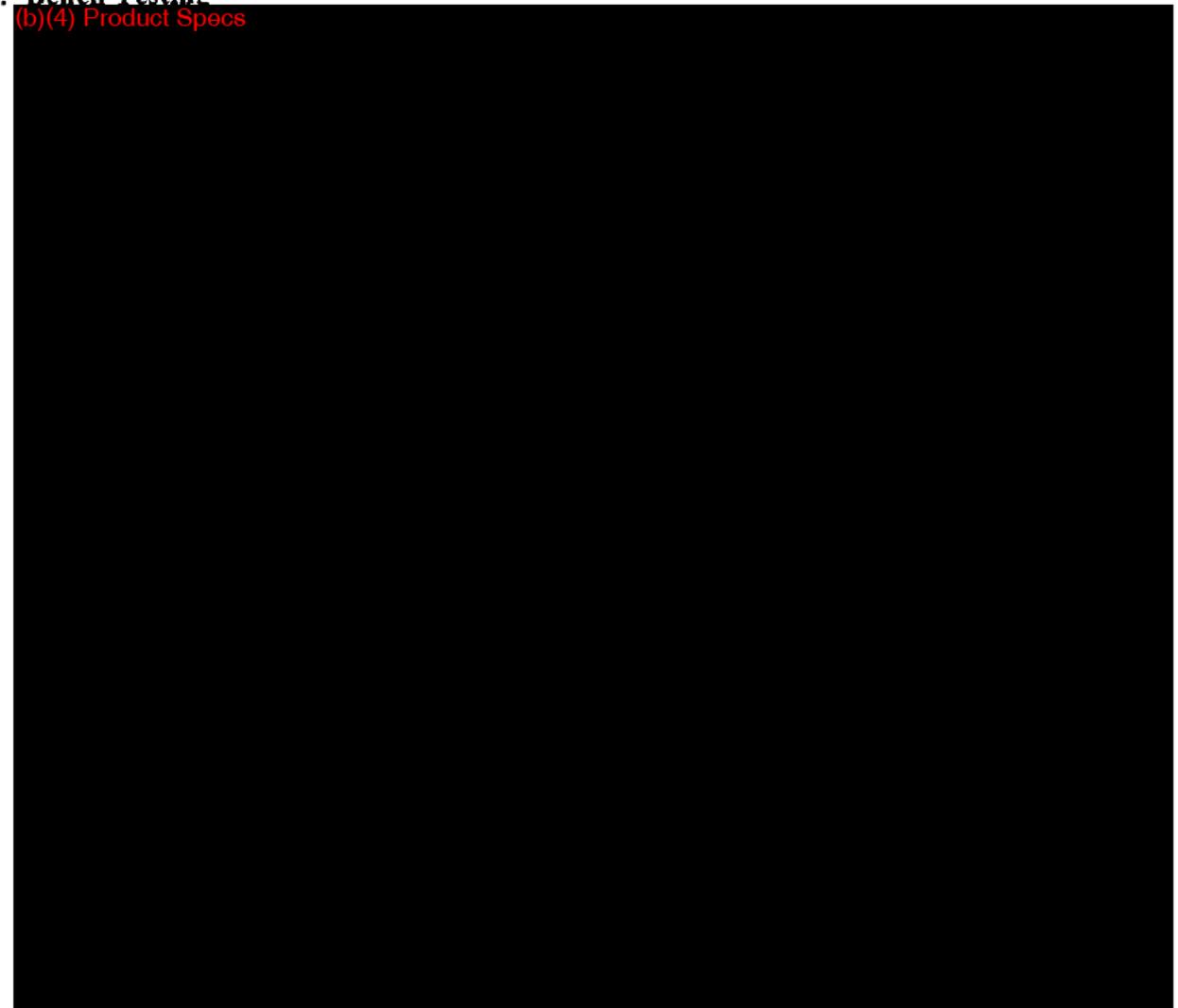
(b) (4)



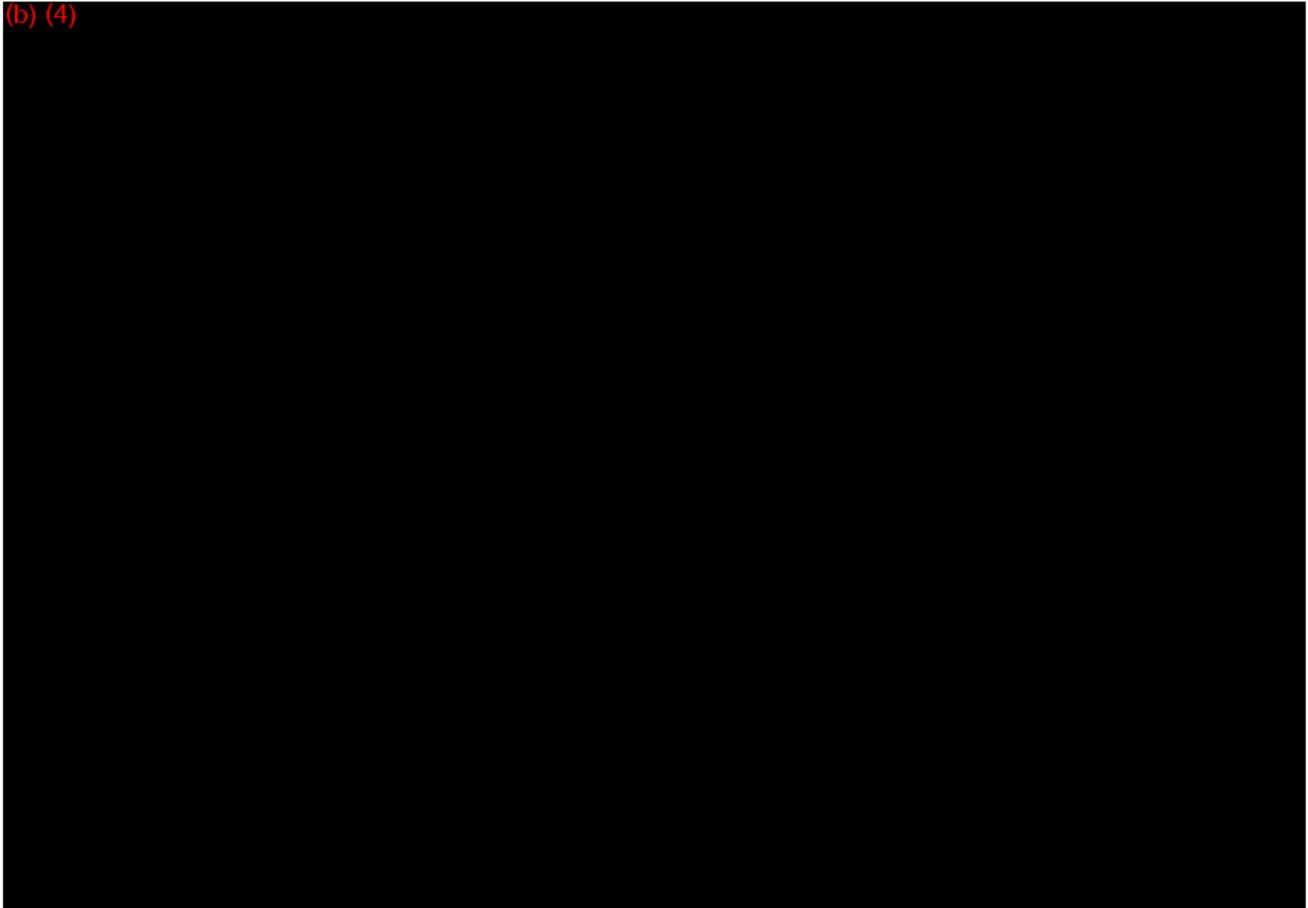
(b) (4)



**B. Bench Testing**  
(b)(4) Product Specs



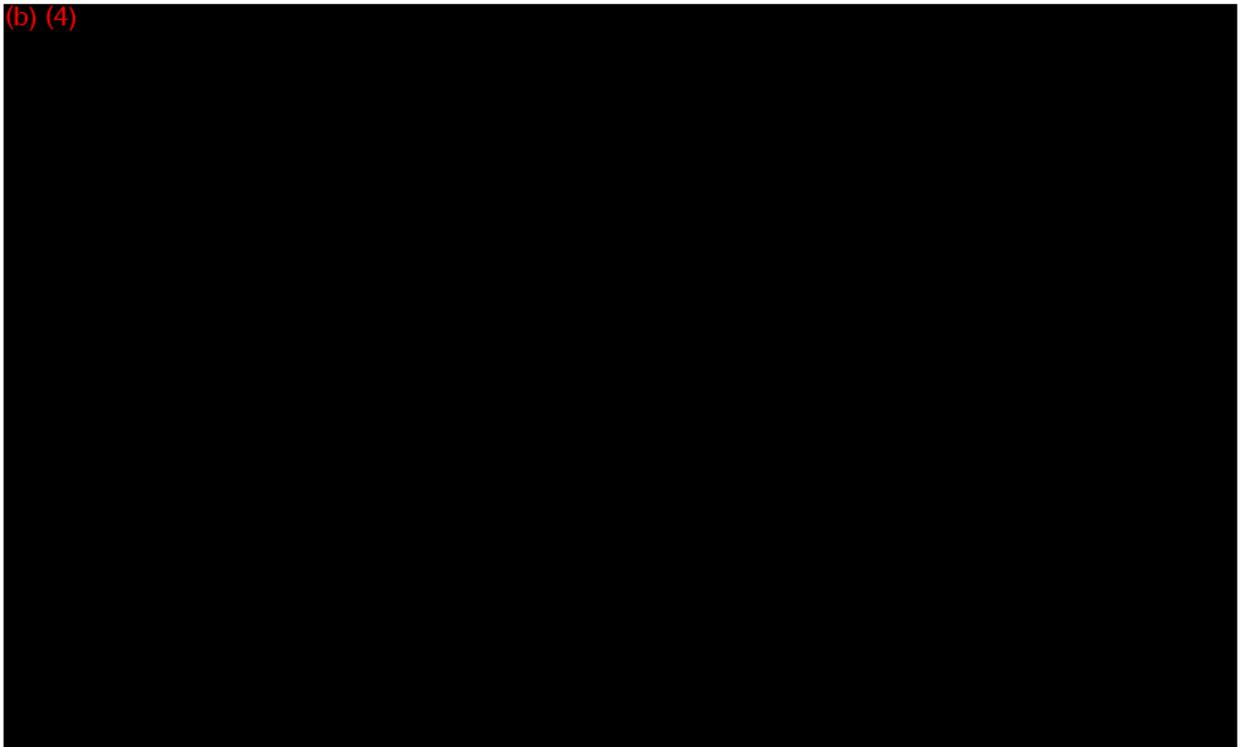
(b) (4)



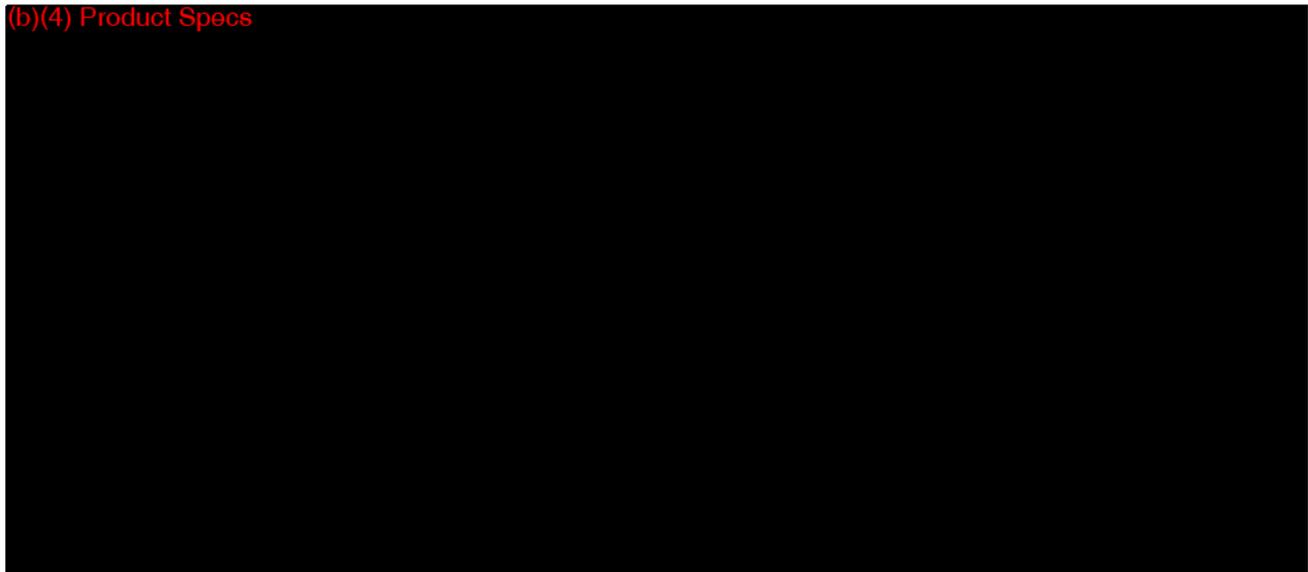
*Deficiency:*

[Redacted] [Redacted] [Redacted] [Redacted] (b) (4)

(b) (4)

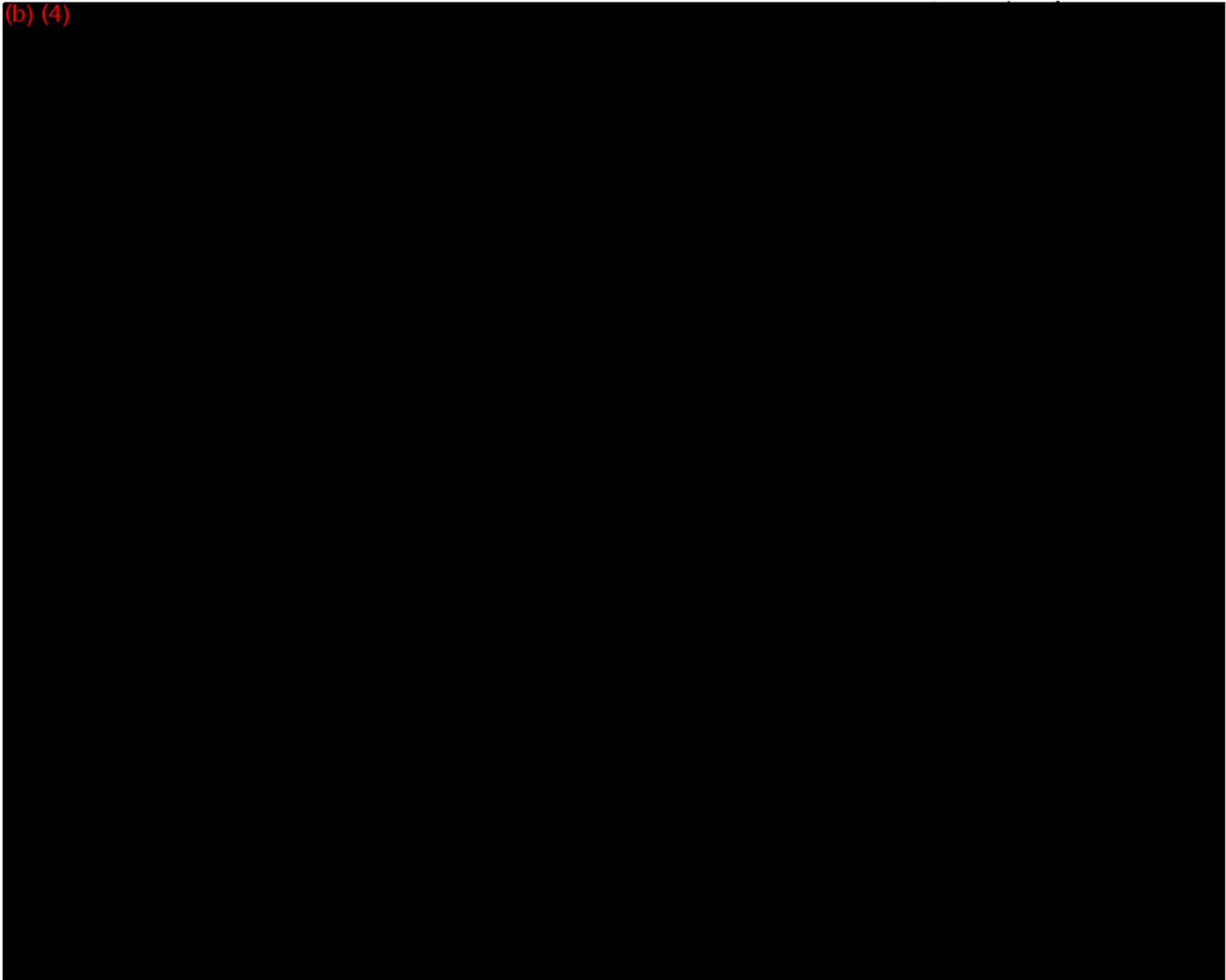


(b)(4) Product Specs



**C. Animal Studies**

(b) (4)



**E. Clinical Data**

[Redacted] (b)

**V. Manufacturing and Processing**

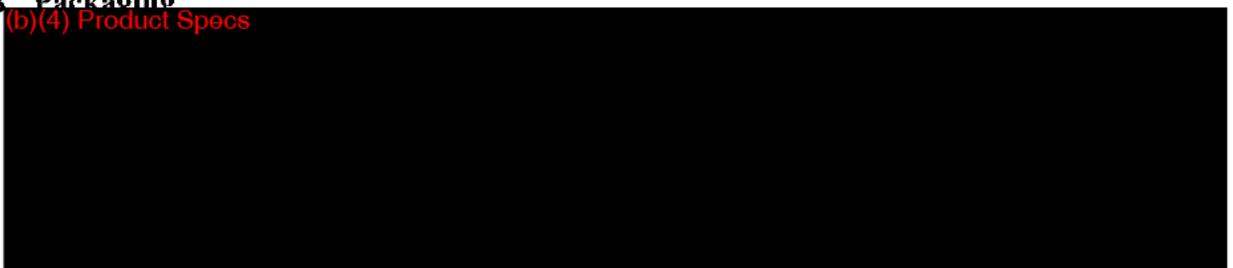
**A. Sterility**

(b)(4) Product Specs



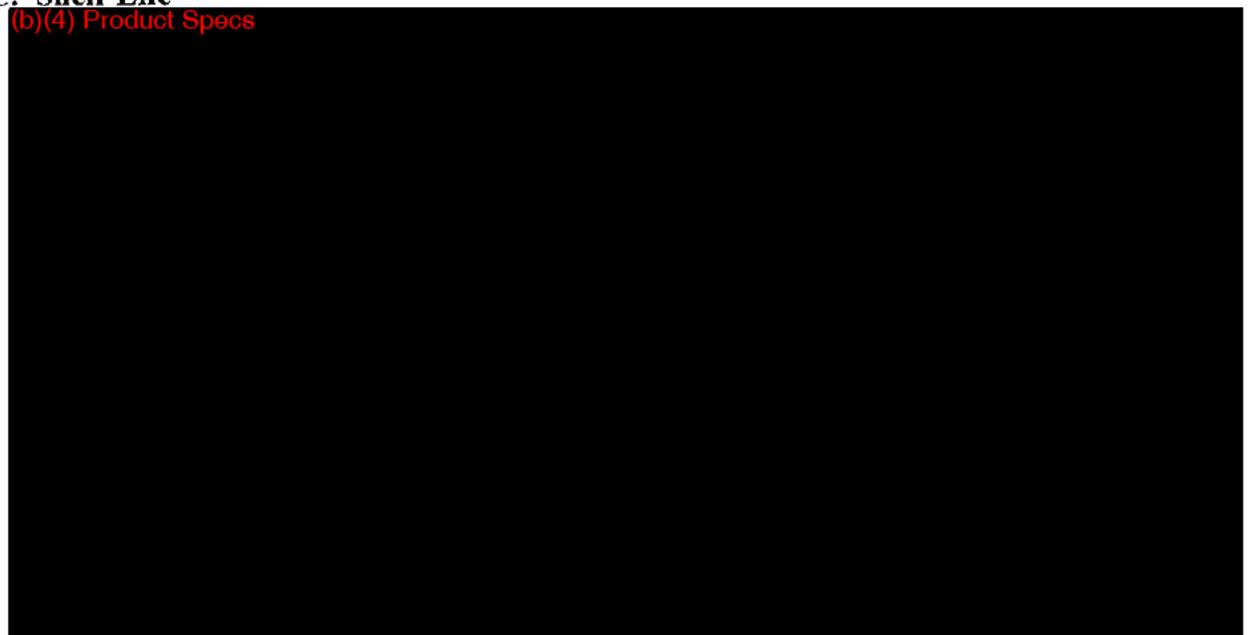
**B. Packaging**

(b)(4) Product Specs



**C. Shelf-Life**

(b)(4) Product Specs



**D. Labeling / IFU**  
**(b)(4) Product Specs**



**VI. Substantial Equivalence**

The manufacturer states that the proposed device is substantially equivalent to their currently marketed CLiRpath Excimer Laser Catheters (K040067).

*Indications for Use:* The current device has the same indications for use as the currently marketed devices.

*Device Design:* The devices are designed similarly with the exception that the current device possesses more optical fibers, and the laser can be operated continuously.

*Materials:* The materials of construction are nearly identical to the predicate materials. One notable exception is the hydrophilic coating that the current device contains.

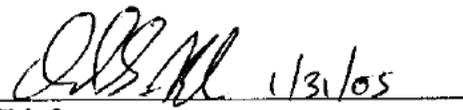
*Performance:* The current and predicate devices share a similar principle of operation. The Turbo device appears to ablate tissue faster than the predicate devices, although additional information is required.

Conclusion:

Although additional information is required, the Turbo catheter is similar enough to the predicate CLiRpath catheters to allow this file to proceed.

**Reviewer Recommendation: Additional Information - AI**

  
\_\_\_\_\_  
Kenneth J. Cavanaugh, Jr., Ph.D.  
Biomedical Engineer  
Peripheral Vascular Devices Branch

  
\_\_\_\_\_  
Chief  
Peripheral Vascular Devices Branch

Date: January 26, 2005

To: Kenneth Cavanaugh  
Biomedical Engineer  
PVDB/DCD/ODE (HFZ-450)

From: William K. Riemenschneider, MS  
Biologist  
CSPB/DCD/ODE (HFZ-150)

Through: Stephen L. Hilbert, PhD, MD  
Experimental Pathologist  
CSPB/DCD/ODE (HFZ-150)

Subject: Spetranetics 2.5 Turbo CLiRpath Excimer Laser Catheter Ablation Device (K043465).

[REDACTED] (b) (4)

Device Description:

The device is a 2.5 mm diameter over-the-wire catheter that is designed to transmit laser light to ablate atherosclerotic lesions so that further interventional therapy can be administered. The device has a working length of approximately 110 cm and transmits light from a 308 nm ultraviolet laser (CVX 300 Laser Angioplasty System; P910001).

(b)(4) Product Specs

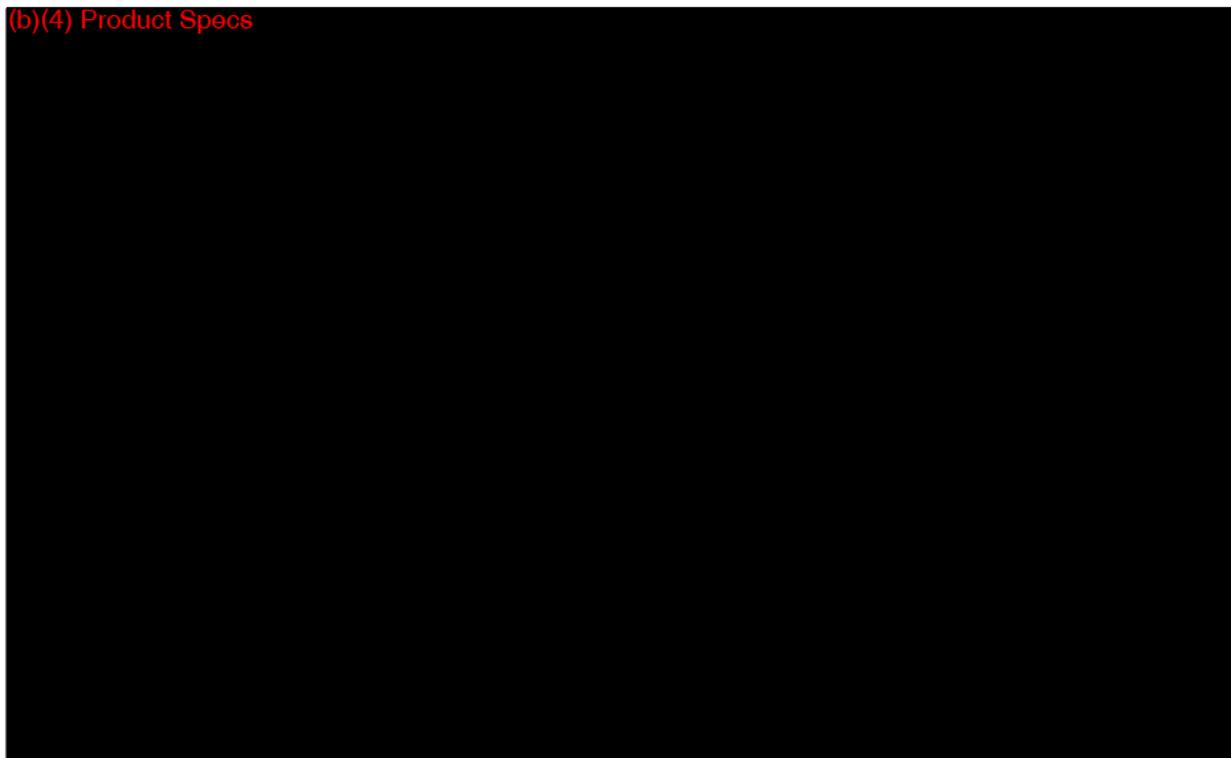
[REDACTED]

Animal Study:

(b)(4) Product Specs

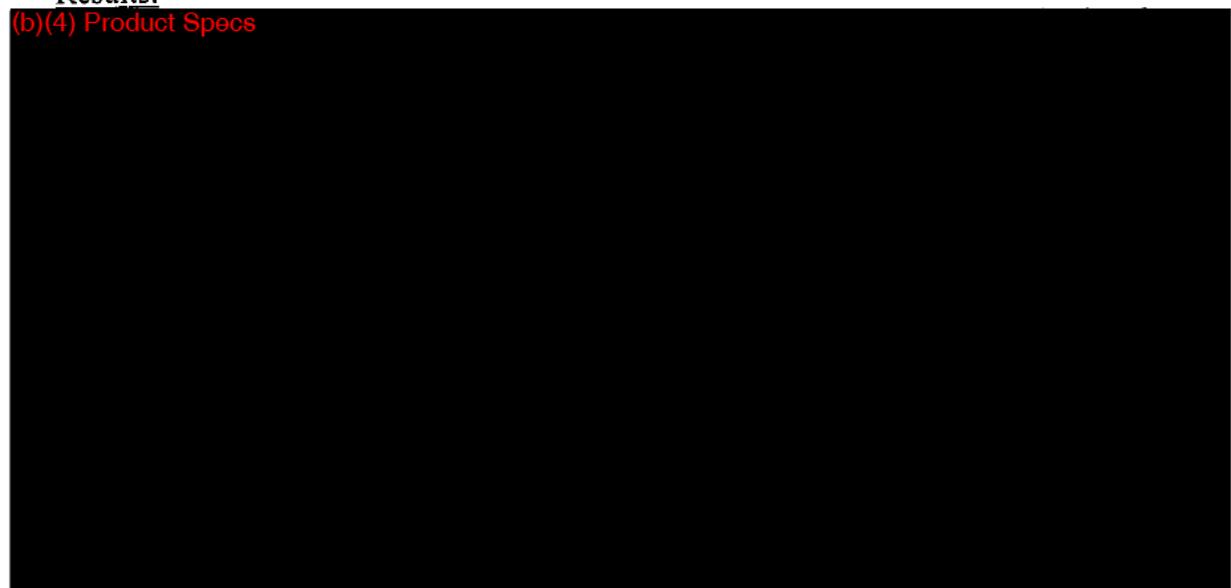
[REDACTED]

(b)(4) Product Specs



Results:

(b)(4) Product Specs



Reviewer Comments:

(b)(4) Product Specs

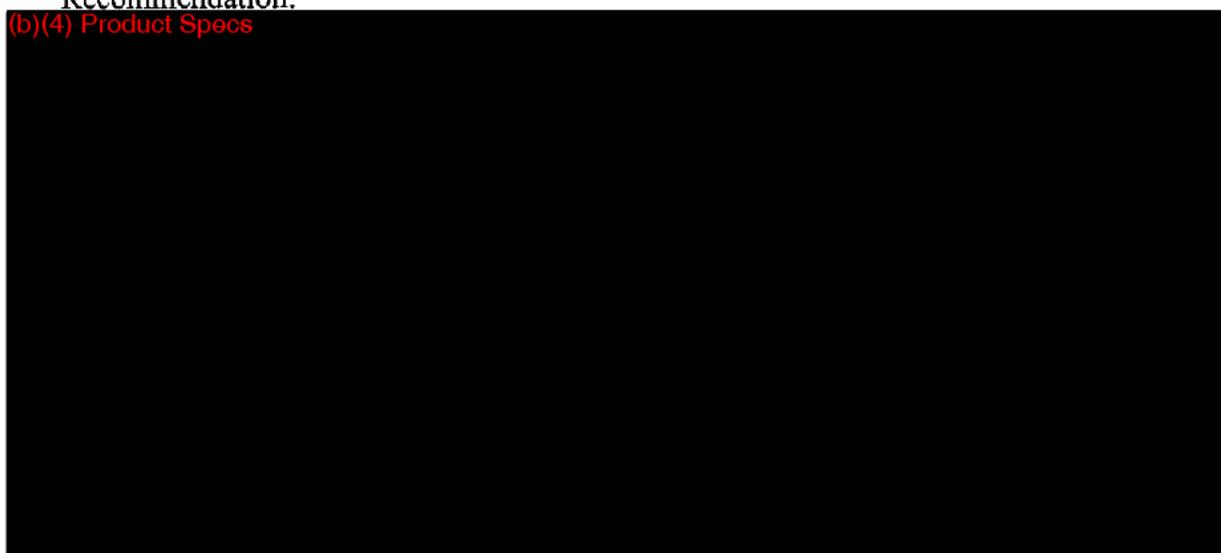


(b)(4) Product Specs

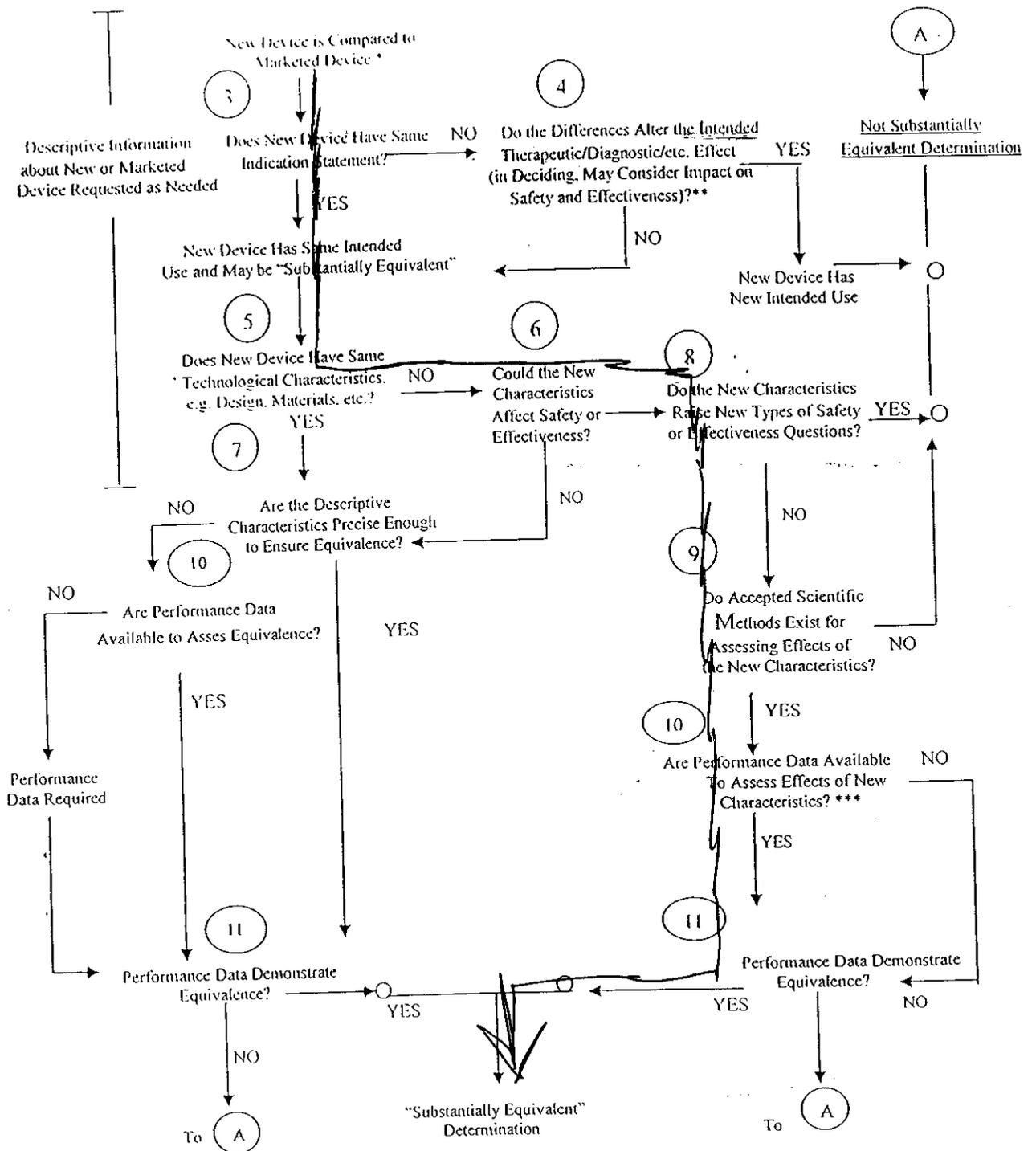
A large black rectangular redaction box covering the majority of the top section of the page.

Recommendation:

(b)(4) Product Specs

A large black rectangular redaction box covering the majority of the middle section of the page.

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



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

July 05, 2005

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

SPECTRANETICS CORP.  
96 TALAMINE CT.  
COLORADO SPRINGS, CO 80907  
ATTN: ADRIAN E. ELFE

510(k) Number: K043465  
Product: 2.5 MM TURBO  
CLIRPATH EXCIMER  
LASER CATHETER,  
MODEL 225-011

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. 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 [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

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

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

Sincerely yours,

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

**Spectranetics**<sup>®</sup>

*we get your blood flowing™*

K043465/S'

Neil Burris  
Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, Colorado 80907

30 June 2005

Dr. Kenneth Cavanaugh  
C/o Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

RE: K043465  
2.5 mm Turbo CLiRpath Excimer Laser Catheter

Dear Dr. Cavanaugh:

The Spectranetics Corporation is responding to your request for additional information regarding pre-market notification K043465 (2.5 mm Turbo CLiRpath Excimer Laser Catheter), which was dated 31 January 2005.

The following responses are presented in the same order as that in which the agency's letter made the requests. Your requests have been paraphrased prior to each response.

Please contact me (Neil Burris; 719 442 2456 phone, [neil.burris@spectranetics.com](mailto:neil.burris@spectranetics.com) e-mail) or Adrian Elfe (719 442 2425 phone, [adrian.elfe@spectranetics.com](mailto:adrian.elfe@spectranetics.com)) with any further requests or comments.

Sincerely,

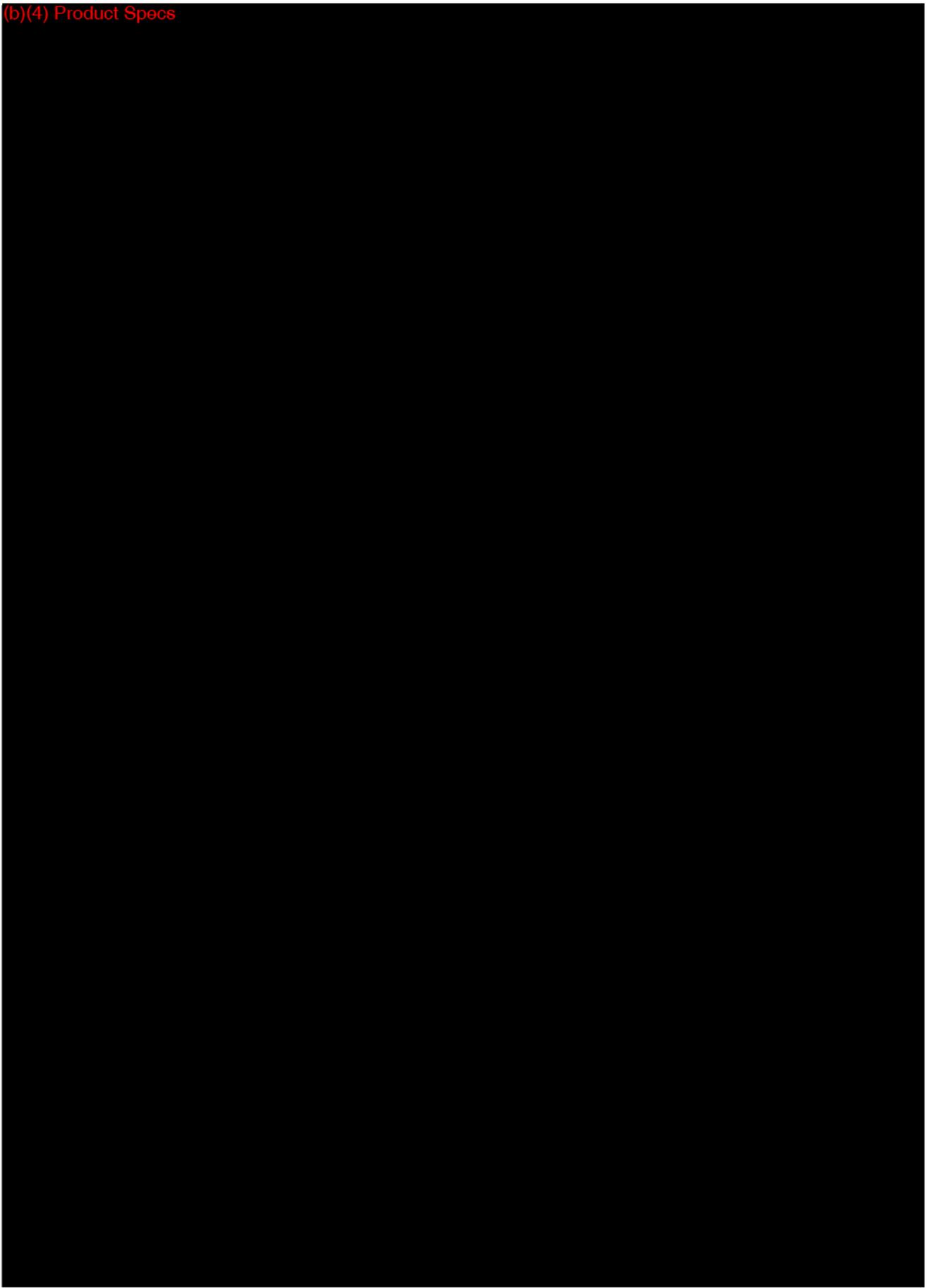


Neil Burris  
Clinical Data Services

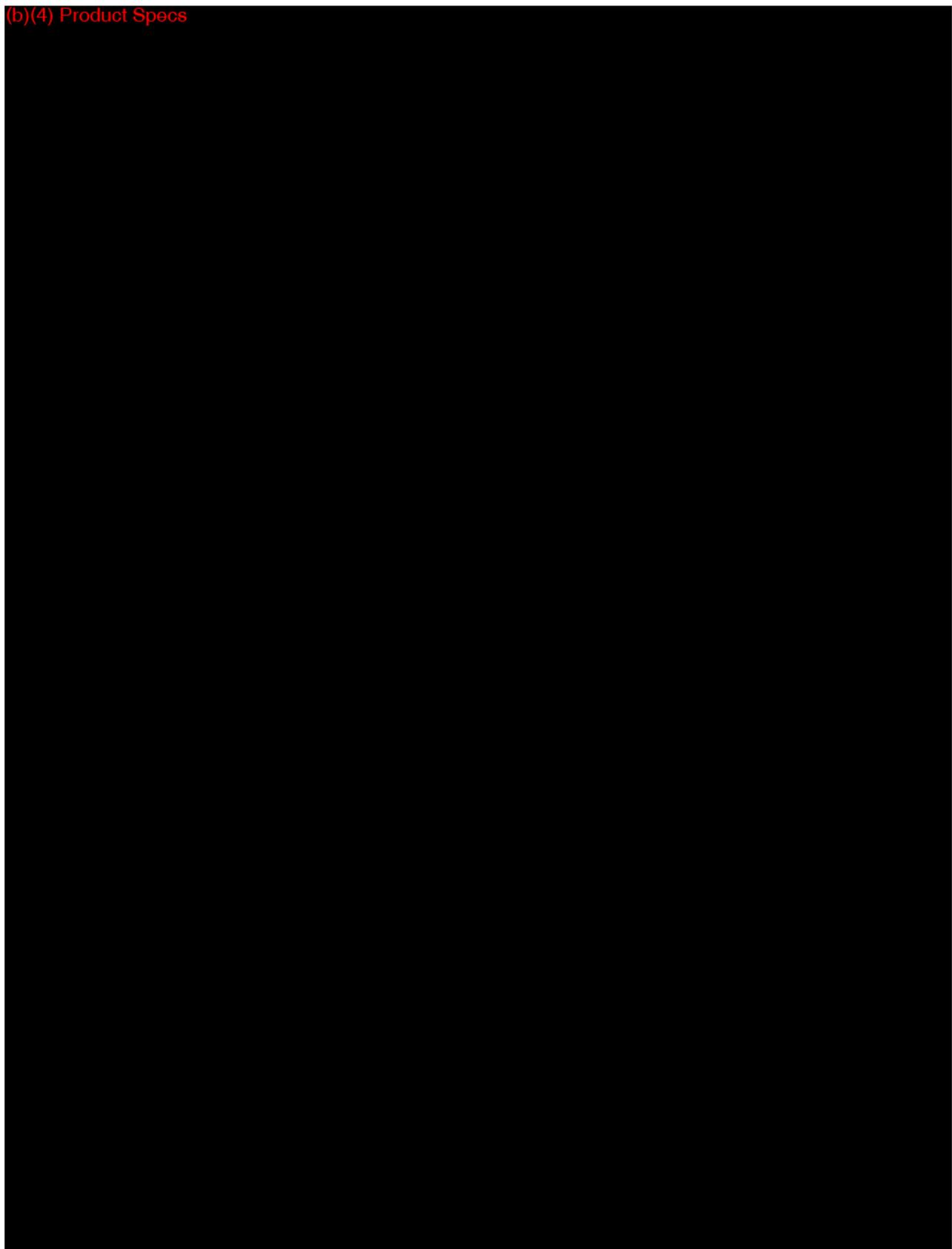
FOIA(b) (7) - D  
DATE: 07/19/05  
TIME: 11:49:26

237 SK1

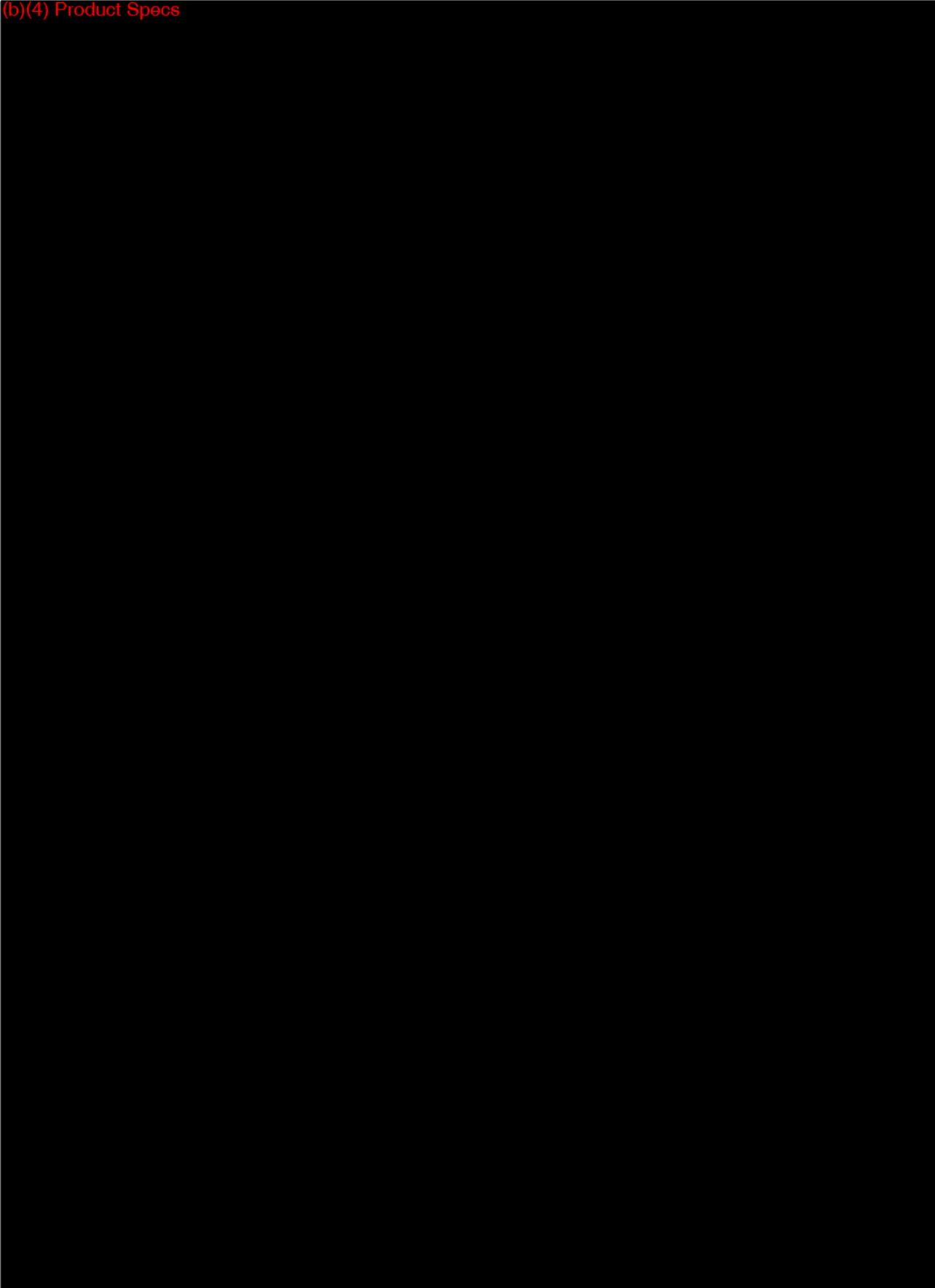
(b)(4) Product Specs



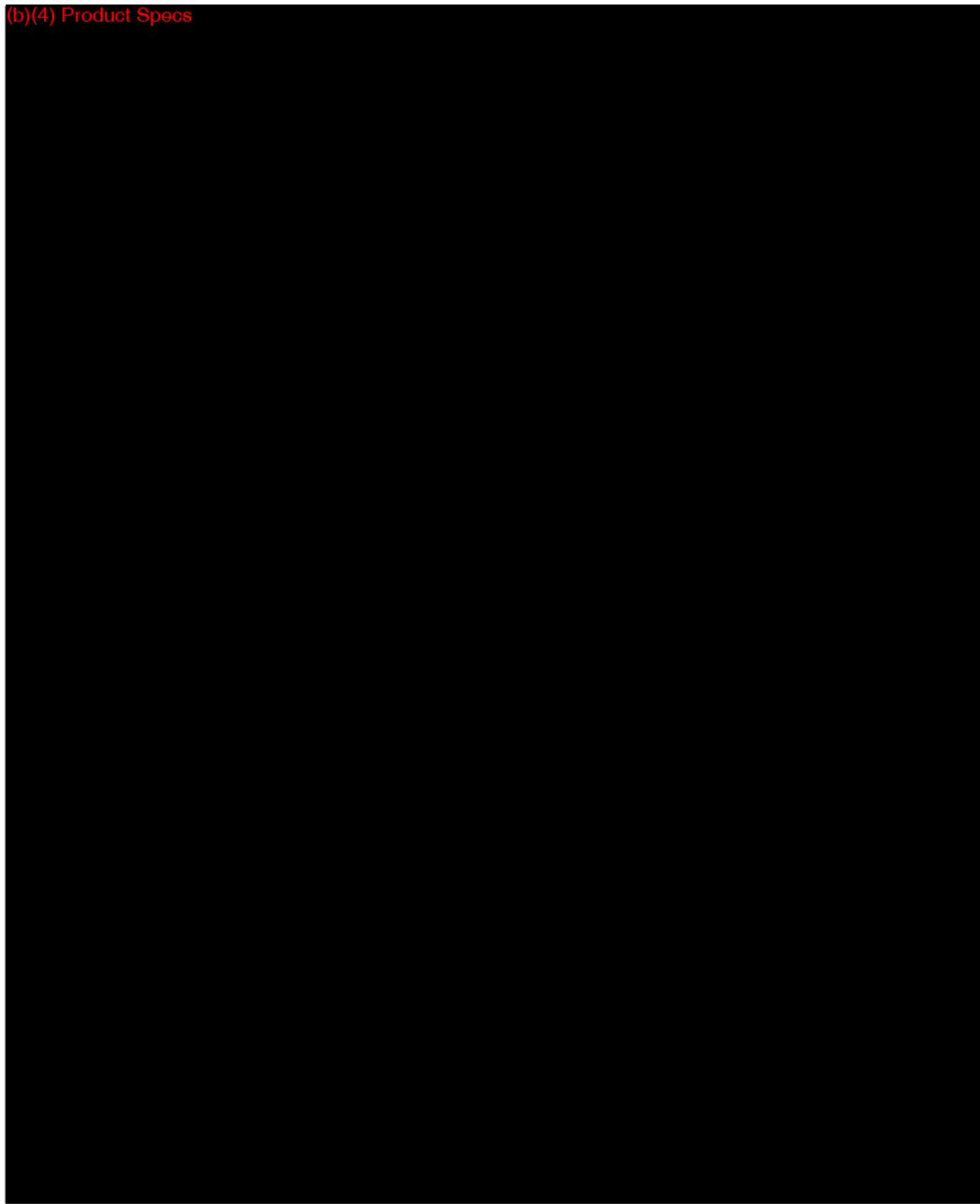
(b)(4) Product Specs



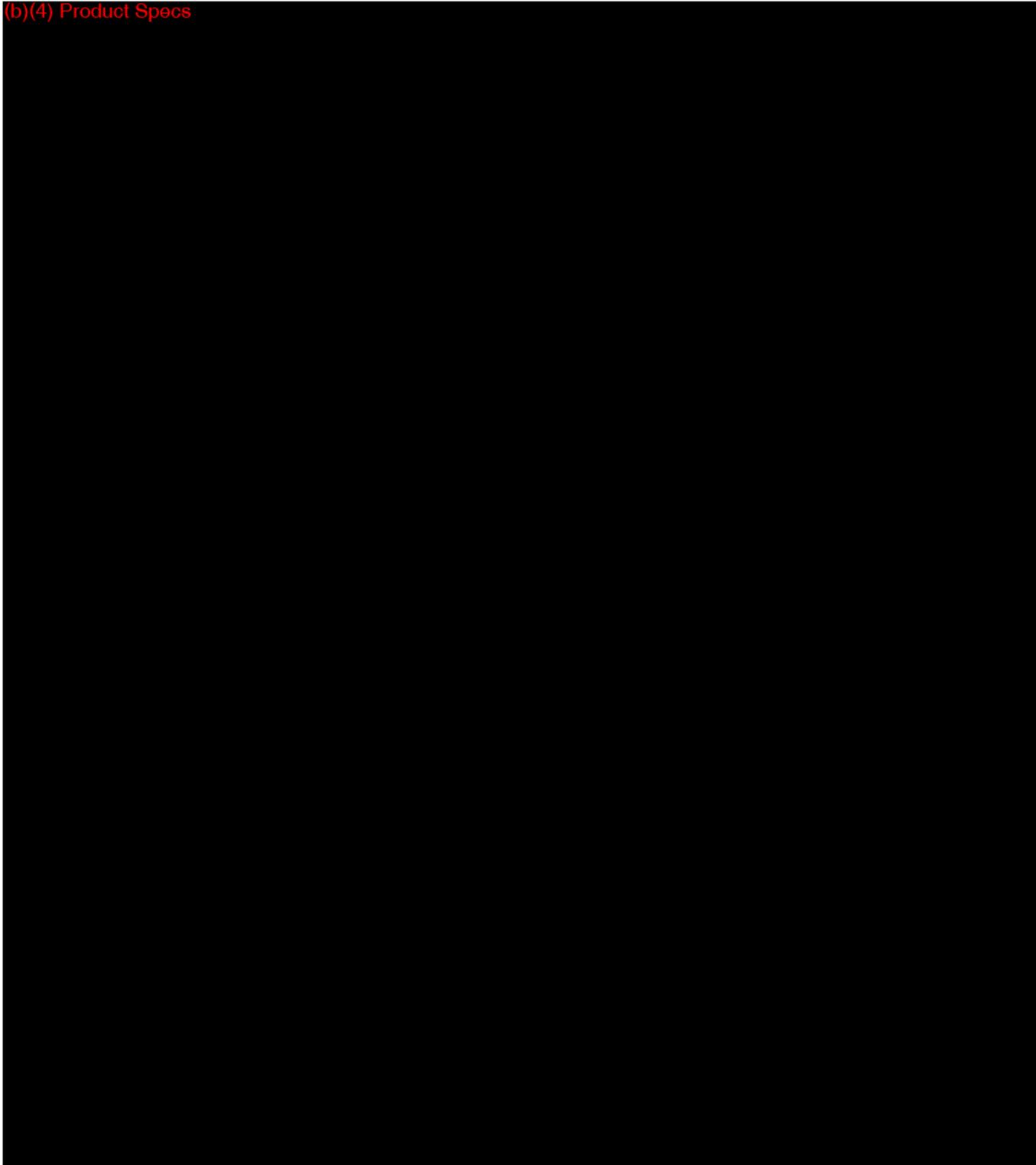
(b)(4) Product Specs



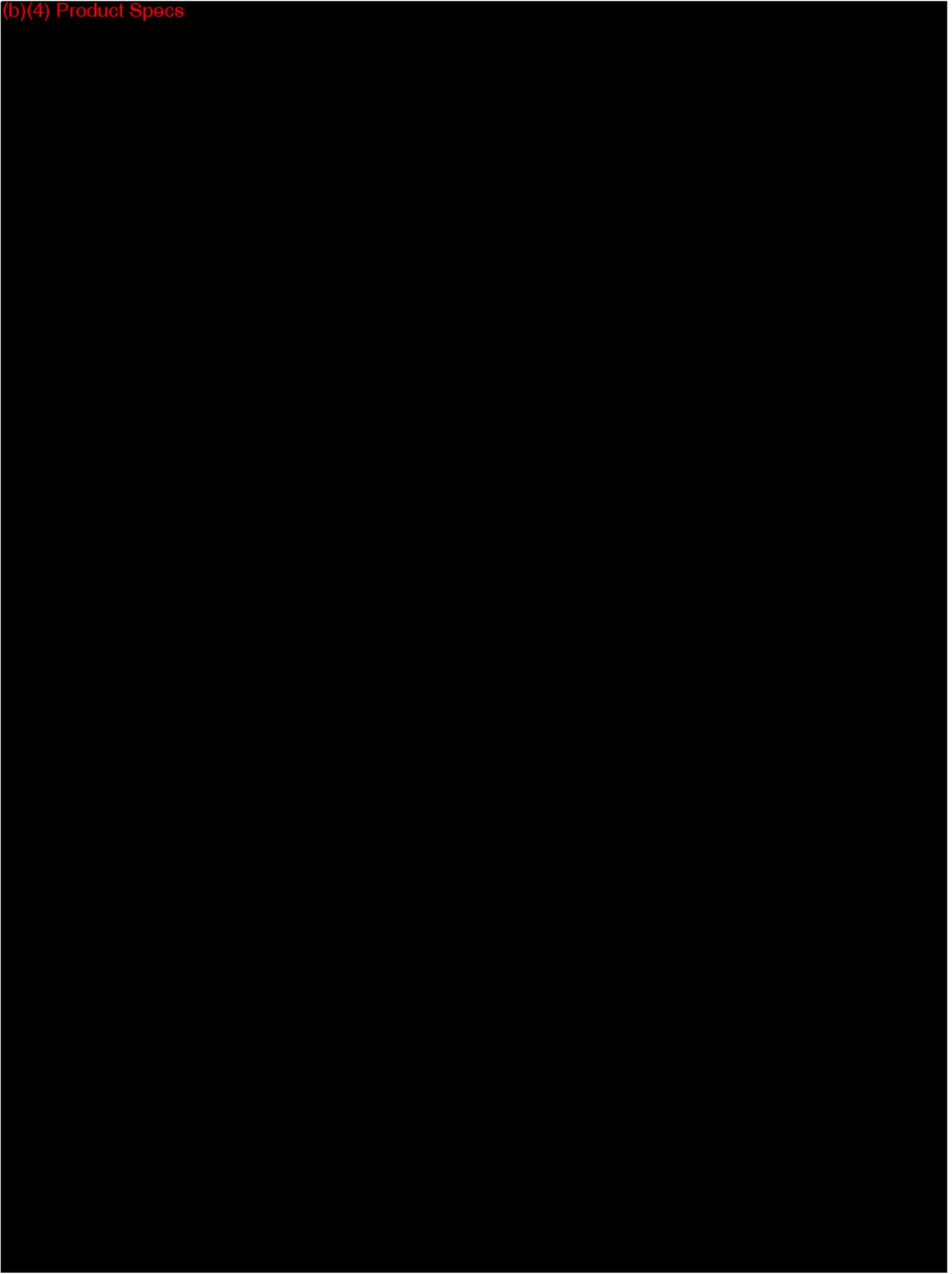
(b)(4) Product Specs



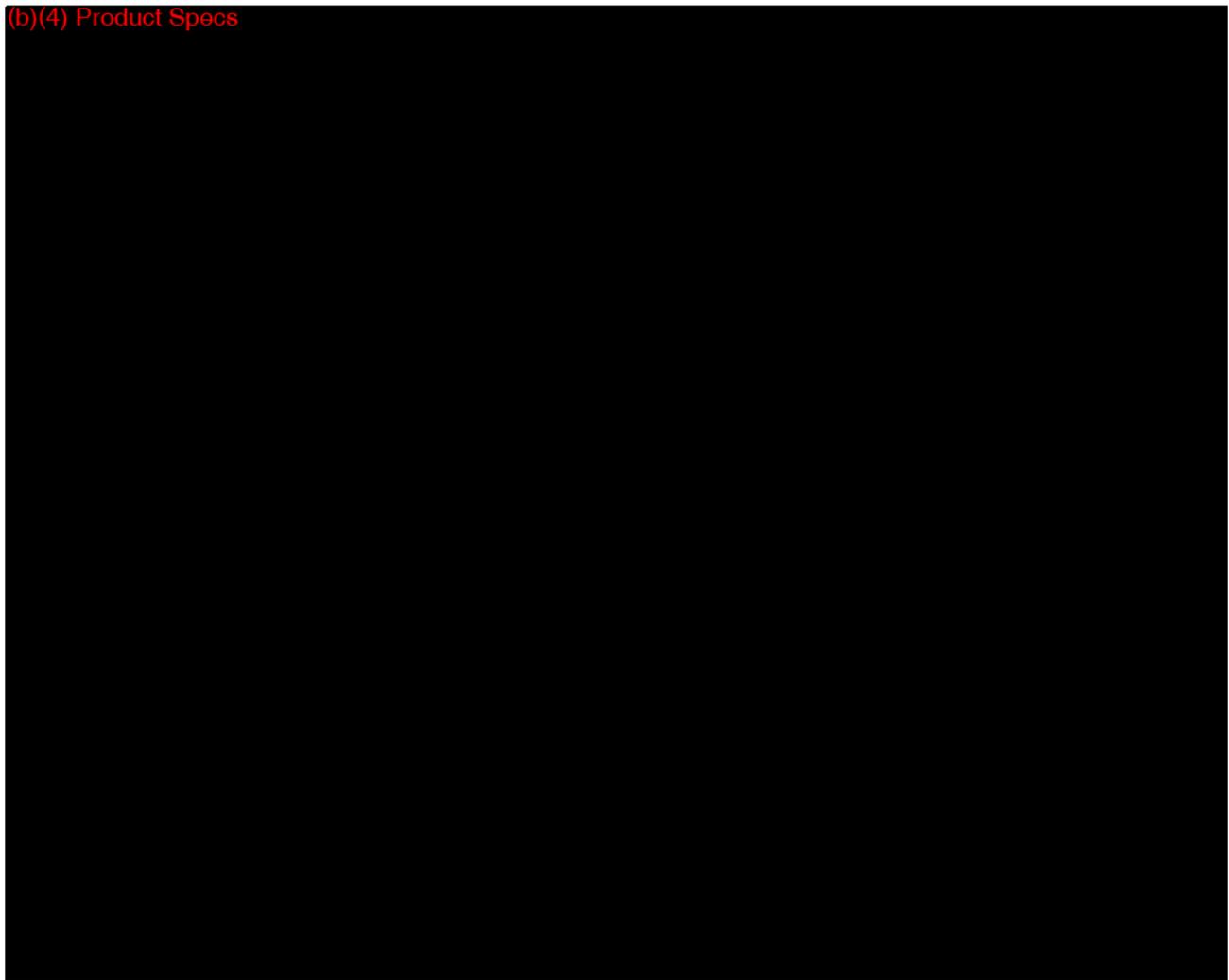
(b)(4) Product Specs



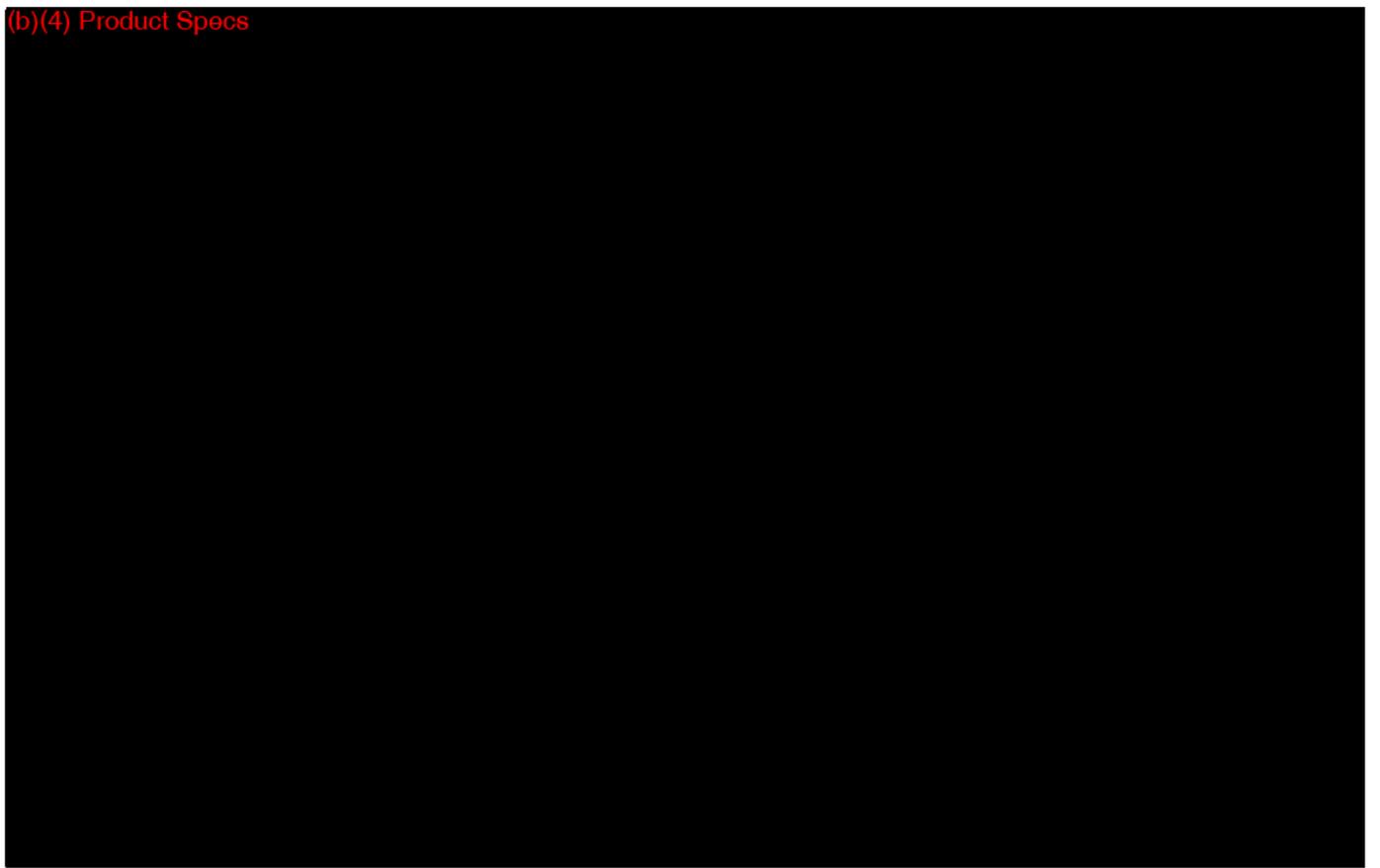
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs





































































































































































































h043465

















































































































































































THIS PAGE DELIBERATELY LEFT BLANK





























































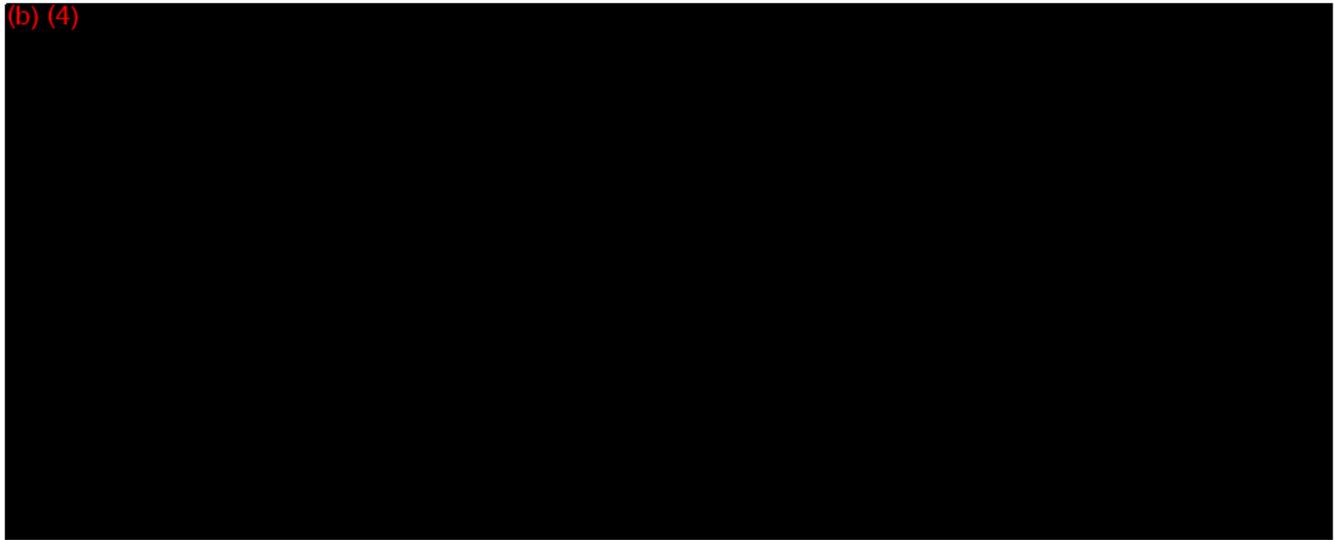








(b) (4)























































RESULTS

PAGE 6 OF 146

**APPENDIX 1**







**APPENDIX 2**

























































































































































































































































































































































































































































































## Appendix 1

SPECTRANETICS CORPORATION

MEMO

To: Joe Brazil  
Rich Peterson

From: Michael Ryan *MJR*

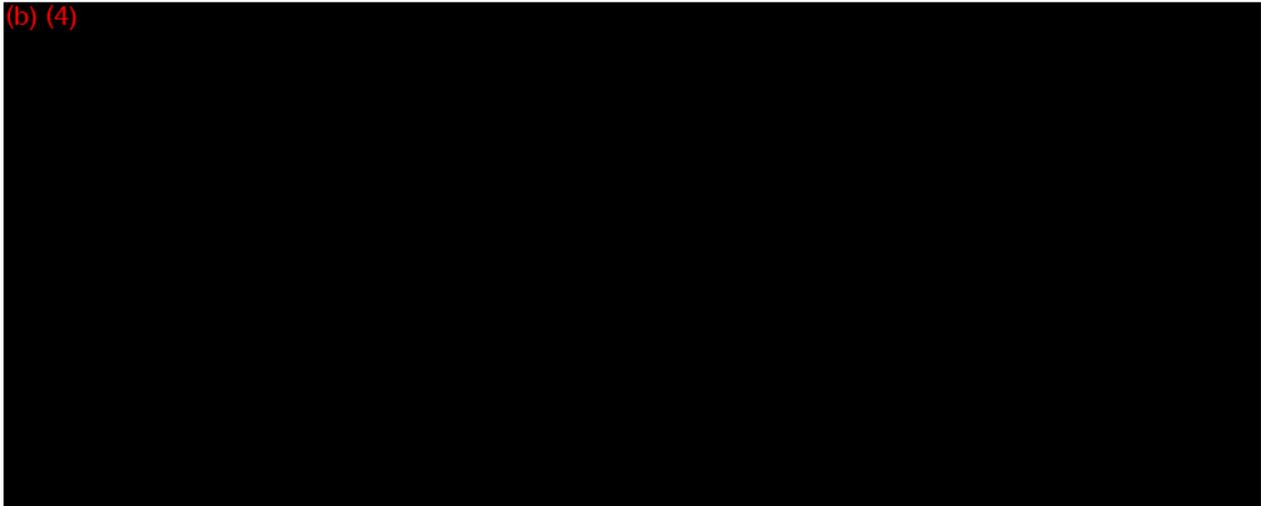
Date: 17 December 2004

RE: Quarterly Bioburden & Cytotoxicity Sample Request

cc: Nancy Hughey

---

(b) (4)



MJR

















































2ml each

SPECS		25 ml BOTTLE		VETER		PARTS	
Model	225-011	Lot	AB 6652 A	Design	18	Serial	10/1/81
Operation / Part Description	QTY	Part No.	QTY	Part No.	QTY	Part No.	QTY
010 Start and Stand	1	1004-01	1	1004-01	1	1004-01	1
011 Tip	1	1004-01	1	1004-01	1	1004-01	1
012 Band	1	1004-01	1	1004-01	1	1004-01	1
013 Inner Assembly	1	1004-01	1	1004-01	1	1004-01	1
014 Outer Jacket	1	1004-01	1	1004-01	1	1004-01	1
015 Seal Tubing	1	1004-01	1	1004-01	1	1004-01	1
016 Powder	1	1004-01	1	1004-01	1	1004-01	1
017 Perma-Seal	1	1004-01	1	1004-01	1	1004-01	1
020 Wick	1	1004-01	1	1004-01	1	1004-01	1
022 Part Epoxy Resin BAND	1	1004-01	1	1004-01	1	1004-01	1
030 Out Tip Vial Wick Length	1	1004-01	1	1004-01	1	1004-01	1
040 Heat Blend Jacket & Round Tip	1	1004-01	1	1004-01	1	1004-01	1
050 Underlay Mat	1	1004-01	1	1004-01	1	1004-01	1
060 Polishing	1	1004-01	1	1004-01	1	1004-01	1
060 Assembly Leak Test Bifurcate	1	1004-01	1	1004-01	1	1004-01	1
070 Shrink Tube	1	1004-01	1	1004-01	1	1004-01	1
070 Bifurcate Cover	1	1004-01	1	1004-01	1	1004-01	1
070 Locking	1	1004-01	1	1004-01	1	1004-01	1
070 Prep Proximal Coupler	1	1004-01	1	1004-01	1	1004-01	1
070 Prox. Strain Relief	1	1004-01	1	1004-01	1	1004-01	1
070 Shrink Tube	1	1004-01	1	1004-01	1	1004-01	1
070 Part Epoxy Resin BAND	1	1004-01	1	1004-01	1	1004-01	1
080 Midline Proximal Coupler	1	1004-01	1	1004-01	1	1004-01	1
080 Slide	1	1004-01	1	1004-01	1	1004-01	1
080 Fiber Foot Clamp	1	1004-01	1	1004-01	1	1004-01	1
080 Metal Clamp	1	1004-01	1	1004-01	1	1004-01	1
080 Screw 2.56 x 1/8 Oleted Pan	1	1004-01	1	1004-01	1	1004-01	1
080 Prox Handle w/Fiber Protector	1	1004-01	1	1004-01	1	1004-01	1
080 Prox Handle w/PHS	1	1004-01	1	1004-01	1	1004-01	1
080 Screw 2.56 x 1/8	1	1004-01	1	1004-01	1	1004-01	1
080 Coat Work Tip Length	1	1004-01	1	1004-01	1	1004-01	1
080 Slide Fiber Coat	1	1004-01	1	1004-01	1	1004-01	1
090 Laser Test	1	1004-01	1	1004-01	1	1004-01	1
100 QA Inspection	1	1004-01	1	1004-01	1	1004-01	1
110 Label/Package	1	1004-01	1	1004-01	1	1004-01	1
120 QA Inspect Package	1	1004-01	1	1004-01	1	1004-01	1
130 Release Clasp	1	1004-01	1	1004-01	1	1004-01	1

701051007



*2-4-1984*

SPECTRANETICS 25 mil No. TRAVELER

Model: 225-011 Lot: AB 6652 A Date: 10/11/64

Operation: Part Description: OPERATOR: Date: GRAN: 10/11/64

Part No.	Description	Operator	Date	Gran	Lot No.
010	3 ft Hand Stand	Down	10/11/64		
011	Filter				
012	Band				
013	Filter Assembly				
014	Outer Jacket				
015	Ball Milling				
016	Powder				
017	Polmer Sleeve				
020	Wide	Down	10/11/64		
021	24 Part Eptek 360 ND				
030	Coupler/Vent/Wick Length	Down	10/11/64		
040	Heat Blend Jacket/Round Top				
050	Underlayment				
050	Polish	Callie	11/16/64		
060	Assembly/Leak Test/Bifurcate	Down	11/16/64		
070	Shrink Tube				
070	Bifurcate Cover				
070	Headle 452				
070	Prox Proximal Coupler	Down	11/16/64		
070	Prox Strain Relief				
070	Shrink Tube 1/8"				
070	24 Part Eptek 360 ND				
080	Mount Proximal Coupler	Down	11/19/64		
080	Slide				
080	Ball Milling				
080	Ball Clamp				
080	Screw 2-56 X 1/8 Slotted Pan Va				
080	Prox Handle w/Filter Protection				
080	Prox Handle w/Rins				
080	Screw 2-56 X 3/16				
080	Coax Work Up Length				
080	Micro Electro Oath				
090	Test				
100	QA Inspection				
110	QA Inspection				
120	QA Inspection				
130	Release to G				

Comments: 225-011 33 25 mil No. TRAVELER

Material used was deca epoxy resin...  
 Used Vented Brown 300...  
 010-015...  
 016-017...  
 018-019...  
 020-021...  
 022-023...  
 024-025...  
 026-027...  
 028-029...  
 030-031...  
 032-033...  
 034-035...  
 036-037...  
 038-039...  
 040-041...  
 042-043...  
 044-045...  
 046-047...  
 048-049...  
 050-051...  
 052-053...  
 054-055...  
 056-057...  
 058-059...  
 060-061...  
 062-063...  
 064-065...  
 066-067...  
 068-069...  
 070-071...  
 072-073...  
 074-075...  
 076-077...  
 078-079...  
 080-081...  
 082-083...  
 084-085...  
 086-087...  
 088-089...  
 090-091...  
 092-093...  
 094-095...  
 096-097...  
 098-099...  
 100-101...  
 102-103...  
 104-105...  
 106-107...  
 108-109...  
 110-111...  
 112-113...  
 114-115...  
 116-117...  
 118-119...  
 120-121...  
 122-123...  
 124-125...  
 126-127...  
 128-129...  
 130-131...  
 132-133...  
 134-135...  
 136-137...  
 138-139...  
 140-141...  
 142-143...  
 144-145...  
 146-147...  
 148-149...  
 150-151...  
 152-153...  
 154-155...  
 156-157...  
 158-159...  
 160-161...  
 162-163...  
 164-165...  
 166-167...  
 168-169...  
 170-171...  
 172-173...  
 174-175...  
 176-177...  
 178-179...  
 180-181...  
 182-183...  
 184-185...  
 186-187...  
 188-189...  
 190-191...  
 192-193...  
 194-195...  
 196-197...  
 198-199...  
 200-201...  
 202-203...  
 204-205...  
 206-207...  
 208-209...  
 210-211...  
 212-213...  
 214-215...  
 216-217...  
 218-219...  
 220-221...  
 222-223...  
 224-225...  
 226-227...  
 228-229...  
 230-231...  
 232-233...  
 234-235...  
 236-237...  
 238-239...  
 240-241...  
 242-243...  
 244-245...  
 246-247...  
 248-249...  
 250-251...  
 252-253...  
 254-255...  
 256-257...  
 258-259...  
 260-261...  
 262-263...  
 264-265...  
 266-267...  
 268-269...  
 270-271...  
 272-273...  
 274-275...  
 276-277...  
 278-279...  
 280-281...  
 282-283...  
 284-285...  
 286-287...  
 288-289...  
 290-291...  
 292-293...  
 294-295...  
 296-297...  
 298-299...  
 300-301...  
 302-303...  
 304-305...  
 306-307...  
 308-309...  
 310-311...  
 312-313...  
 314-315...  
 316-317...  
 318-319...  
 320-321...  
 322-323...  
 324-325...  
 326-327...  
 328-329...  
 330-331...  
 332-333...  
 334-335...  
 336-337...  
 338-339...  
 340-341...  
 342-343...  
 344-345...  
 346-347...  
 348-349...  
 350-351...  
 352-353...  
 354-355...  
 356-357...  
 358-359...  
 360-361...  
 362-363...  
 364-365...  
 366-367...  
 368-369...  
 370-371...  
 372-373...  
 374-375...  
 376-377...  
 378-379...  
 380-381...  
 382-383...  
 384-385...  
 386-387...  
 388-389...  
 390-391...  
 392-393...  
 394-395...  
 396-397...  
 398-399...  
 400-401...  
 402-403...  
 404-405...  
 406-407...  
 408-409...  
 410-411...  
 412-413...  
 414-415...  
 416-417...  
 418-419...  
 420-421...  
 422-423...  
 424-425...  
 426-427...  
 428-429...  
 430-431...  
 432-433...  
 434-435...  
 436-437...  
 438-439...  
 440-441...  
 442-443...  
 444-445...  
 446-447...  
 448-449...  
 450-451...  
 452-453...  
 454-455...  
 456-457...  
 458-459...  
 460-461...  
 462-463...  
 464-465...  
 466-467...  
 468-469...  
 470-471...  
 472-473...  
 474-475...  
 476-477...  
 478-479...  
 480-481...  
 482-483...  
 484-485...  
 486-487...  
 488-489...  
 490-491...  
 492-493...  
 494-495...  
 496-497...  
 498-499...  
 500-501...  
 502-503...  
 504-505...  
 506-507...  
 508-509...  
 510-511...  
 512-513...  
 514-515...  
 516-517...  
 518-519...  
 520-521...  
 522-523...  
 524-525...  
 526-527...  
 528-529...  
 530-531...  
 532-533...  
 534-535...  
 536-537...  
 538-539...  
 540-541...  
 542-543...  
 544-545...  
 546-547...  
 548-549...  
 550-551...  
 552-553...  
 554-555...  
 556-557...  
 558-559...  
 560-561...  
 562-563...  
 564-565...  
 566-567...  
 568-569...  
 570-571...  
 572-573...  
 574-575...  
 576-577...  
 578-579...  
 580-581...  
 582-583...  
 584-585...  
 586-587...  
 588-589...  
 590-591...  
 592-593...  
 594-595...  
 596-597...  
 598-599...  
 600-601...  
 602-603...  
 604-605...  
 606-607...  
 608-609...  
 610-611...  
 612-613...  
 614-615...  
 616-617...  
 618-619...  
 620-621...  
 622-623...  
 624-625...  
 626-627...  
 628-629...  
 630-631...  
 632-633...  
 634-635...  
 636-637...  
 638-639...  
 640-641...  
 642-643...  
 644-645...  
 646-647...  
 648-649...  
 650-651...  
 652-653...  
 654-655...  
 656-657...  
 658-659...  
 660-661...  
 662-663...  
 664-665...  
 666-667...  
 668-669...  
 670-671...  
 672-673...  
 674-675...  
 676-677...  
 678-679...  
 680-681...  
 682-683...  
 684-685...  
 686-687...  
 688-689...  
 690-691...  
 692-693...  
 694-695...  
 696-697...  
 698-699...  
 700-701...  
 702-703...  
 704-705...  
 706-707...  
 708-709...  
 710-711...  
 712-713...  
 714-715...  
 716-717...  
 718-719...  
 720-721...  
 722-723...  
 724-725...  
 726-727...  
 728-729...  
 730-731...  
 732-733...  
 734-735...  
 736-737...  
 738-739...  
 740-741...  
 742-743...  
 744-745...  
 746-747...  
 748-749...  
 750-751...  
 752-753...  
 754-755...  
 756-757...  
 758-759...  
 760-761...  
 762-763...  
 764-765...  
 766-767...  
 768-769...  
 770-771...  
 772-773...  
 774-775...  
 776-777...  
 778-779...  
 780-781...  
 782-783...  
 784-785...  
 786-787...  
 788-789...  
 790-791...  
 792-793...  
 794-795...  
 796-797...  
 798-799...  
 800-801...  
 802-803...  
 804-805...  
 806-807...  
 808-809...  
 810-811...  
 812-813...  
 814-815...  
 816-817...  
 818-819...  
 820-821...  
 822-823...  
 824-825...  
 826-827...  
 828-829...  
 830-831...  
 832-833...  
 834-835...  
 836-837...  
 838-839...  
 840-841...  
 842-843...  
 844-845...  
 846-847...  
 848-849...  
 850-851...  
 852-853...  
 854-855...  
 856-857...  
 858-859...  
 860-861...  
 862-863...  
 864-865...  
 866-867...  
 868-869...  
 870-871...  
 872-873...  
 874-875...  
 876-877...  
 878-879...  
 880-881...  
 882-883...  
 884-885...  
 886-887...  
 888-889...  
 890-891...  
 892-893...  
 894-895...  
 896-897...  
 898-899...  
 900-901...  
 902-903...  
 904-905...  
 906-907...  
 908-909...  
 910-911...  
 912-913...  
 914-915...  
 916-917...  
 918-919...  
 920-921...  
 922-923...  
 924-925...  
 926-927...  
 928-929...  
 930-931...  
 932-933...  
 934-935...  
 936-937...  
 938-939...  
 940-941...  
 942-943...  
 944-945...  
 946-947...  
 948-949...  
 950-951...  
 952-953...  
 954-955...  
 956-957...  
 958-959...  
 960-961...  
 962-963...  
 964-965...  
 966-967...  
 968-969...  
 970-971...  
 972-973...  
 974-975...  
 976-977...  
 978-979...  
 980-981...  
 982-983...  
 984-985...  
 986-987...  
 988-989...  
 990-991...  
 992-993...  
 994-995...  
 996-997...  
 998-999...  
 1000-1001...

244 records

SPECTRANETICS		25 HUBS TRAVELER		PARTS LIST	
Model No.	Part No.	Part Description	QTY	Unit Price	Total Price
225-011	AB 6652A		25		
010 Start and Strand	C. D. Doolittle	10/15/01			
015 Fiber			3660	11.66	42651.60
020 Band			3660	11.07	40516.20
030 Inner Assembly			3660	11.53	42099.80
040 Outer Jacket			3660	11.62	42519.72
050 Tail Tubing			3660	11.52	42063.60
060 Powder			1600	0.0005	0.80
070 Perma Sleeve			2800	0.0074	20732.00
080 Wick	C. D. Doolittle	10/16/01			
090 2 Part Epo. tek 863ND			1600	0.109	174.40
100 Cut Tip Verify Wick Length	C. D. Doolittle	10/15/01			
110 Heat Blend Jacket & Round Tip	C. D. Doolittle	10/15/01			
120 Underlayment			3660	0.666	24354.60
130 Polish	Challenger	10/15/01			
140 Assemble/Leak Test Bifurcate	Challenger	10/15/01			
150 Fiber Leg			3660	10.28	37630.80
160 Shrink Tubing			2800	0.667	18676.00
170 Bifurcate Cover			3660	10.27	37588.20
180 Bootie 64			3660	0.0574	21000.84
190 Prep Proximal Coupler	Challenger	11/14/01			
200 Prox. Strain Relief			3660	0.865	31659.00
210 Shrink Tube 1/8			2800	0.667	18676.00
220 2 Part Epo. tek 863ND			1600	0.109	174.40
230 Mount Proximal Coupler	Challenger	11/14/01			
240 Slide			3660	12.17	44540.20
250 Fiber Egg W/amp			3660	12.20	44652.00
260 Tail Clamp			3660	10.97	40150.20
270 Screw 2.56 X 3/8 Slotted Pan			2825	0.468	13218.50
280 Prox Handle w/ Fiber Protector			3660	0.660	24138.00
290 Prox Handle w/ Pths			3660	0.261	9533.60
300 Screw 2.56 X 3/16			2825	0.177	5010.25
310 Coax Working Length					
320 Direct Fiber Coating			1600	0.266	425.60
330 Laser Test					
340 QA Inspection					
350 Label/Package					
360 QA Inspection Package					
370 Release to Pack					
Comments: 1. 10/15/01 2. 10/15/01 3. 10/15/01 4. 10/15/01 5. 10/15/01 6. 10/15/01 7. 10/15/01 8. 10/15/01 9. 10/15/01 10. 10/15/01 11. 10/15/01 12. 10/15/01 13. 10/15/01 14. 10/15/01 15. 10/15/01 16. 10/15/01 17. 10/15/01 18. 10/15/01 19. 10/15/01 20. 10/15/01 21. 10/15/01 22. 10/15/01 23. 10/15/01 24. 10/15/01 25. 10/15/01					

*27 p. numbers*

SPECTRANETICS 4511 Turbo TRAVELER

Model	Part No.	Part Description	Operator	Date	S/P/N	Part No.	Part No.
225-011	AB6652A				24		10/5/04
010	Stiff Hand/Stand			10/15/04			
020	Wick						
030	Outer Jacket			10/15/04			010300
040	Heat Shield/Bracket & Round Tip			10/16/04			010310
050	Polish						
060	Assembly/Bracket/Bifurcate			11/18/04			
070	Prox Strain Relief			11/19/04			
080	Mount Proximal Coupler			11/19/04			
090	Case/Rest						
100	Case/Inspection						
110	Case/Inspection						
120	Case/Inspection						
130	Case/Inspection						

Comments: 1. A-1101033 - 11/18/04 - 11/19/04 - 11/20/04 - 11/21/04 - 11/22/04 - 11/23/04 - 11/24/04 - 11/25/04 - 11/26/04 - 11/27/04 - 11/28/04 - 11/29/04 - 11/30/04 - 12/1/04 - 12/2/04 - 12/3/04 - 12/4/04 - 12/5/04 - 12/6/04 - 12/7/04 - 12/8/04 - 12/9/04 - 12/10/04 - 12/11/04 - 12/12/04 - 12/13/04 - 12/14/04 - 12/15/04 - 12/16/04 - 12/17/04 - 12/18/04 - 12/19/04 - 12/20/04 - 12/21/04 - 12/22/04 - 12/23/04 - 12/24/04 - 12/25/04 - 12/26/04 - 12/27/04 - 12/28/04 - 12/29/04 - 12/30/04 - 1/1/05 - 1/2/05 - 1/3/05 - 1/4/05 - 1/5/05 - 1/6/05 - 1/7/05 - 1/8/05 - 1/9/05 - 1/10/05 - 1/11/05 - 1/12/05 - 1/13/05 - 1/14/05 - 1/15/05 - 1/16/05 - 1/17/05 - 1/18/05 - 1/19/05 - 1/20/05 - 1/21/05 - 1/22/05 - 1/23/05 - 1/24/05 - 1/25/05 - 1/26/05 - 1/27/05 - 1/28/05 - 1/29/05 - 1/30/05 - 1/31/05 - 2/1/05 - 2/2/05 - 2/3/05 - 2/4/05 - 2/5/05 - 2/6/05 - 2/7/05 - 2/8/05 - 2/9/05 - 2/10/05 - 2/11/05 - 2/12/05 - 2/13/05 - 2/14/05 - 2/15/05 - 2/16/05 - 2/17/05 - 2/18/05 - 2/19/05 - 2/20/05 - 2/21/05 - 2/22/05 - 2/23/05 - 2/24/05 - 2/25/05 - 2/26/05 - 2/27/05 - 2/28/05 - 2/29/05 - 2/30/05 - 3/1/05 - 3/2/05 - 3/3/05 - 3/4/05 - 3/5/05 - 3/6/05 - 3/7/05 - 3/8/05 - 3/9/05 - 3/10/05 - 3/11/05 - 3/12/05 - 3/13/05 - 3/14/05 - 3/15/05 - 3/16/05 - 3/17/05 - 3/18/05 - 3/19/05 - 3/20/05 - 3/21/05 - 3/22/05 - 3/23/05 - 3/24/05 - 3/25/05 - 3/26/05 - 3/27/05 - 3/28/05 - 3/29/05 - 3/30/05 - 3/31/05 - 4/1/05 - 4/2/05 - 4/3/05 - 4/4/05 - 4/5/05 - 4/6/05 - 4/7/05 - 4/8/05 - 4/9/05 - 4/10/05 - 4/11/05 - 4/12/05 - 4/13/05 - 4/14/05 - 4/15/05 - 4/16/05 - 4/17/05 - 4/18/05 - 4/19/05 - 4/20/05 - 4/21/05 - 4/22/05 - 4/23/05 - 4/24/05 - 4/25/05 - 4/26/05 - 4/27/05 - 4/28/05 - 4/29/05 - 4/30/05 - 5/1/05 - 5/2/05 - 5/3/05 - 5/4/05 - 5/5/05 - 5/6/05 - 5/7/05 - 5/8/05 - 5/9/05 - 5/10/05 - 5/11/05 - 5/12/05 - 5/13/05 - 5/14/05 - 5/15/05 - 5/16/05 - 5/17/05 - 5/18/05 - 5/19/05 - 5/20/05 - 5/21/05 - 5/22/05 - 5/23/05 - 5/24/05 - 5/25/05 - 5/26/05 - 5/27/05 - 5/28/05 - 5/29/05 - 5/30/05 - 5/31/05 - 6/1/05 - 6/2/05 - 6/3/05 - 6/4/05 - 6/5/05 - 6/6/05 - 6/7/05 - 6/8/05 - 6/9/05 - 6/10/05 - 6/11/05 - 6/12/05 - 6/13/05 - 6/14/05 - 6/15/05 - 6/16/05 - 6/17/05 - 6/18/05 - 6/19/05 - 6/20/05 - 6/21/05 - 6/22/05 - 6/23/05 - 6/24/05 - 6/25/05 - 6/26/05 - 6/27/05 - 6/28/05 - 6/29/05 - 6/30/05 - 7/1/05 - 7/2/05 - 7/3/05 - 7/4/05 - 7/5/05 - 7/6/05 - 7/7/05 - 7/8/05 - 7/9/05 - 7/10/05 - 7/11/05 - 7/12/05 - 7/13/05 - 7/14/05 - 7/15/05 - 7/16/05 - 7/17/05 - 7/18/05 - 7/19/05 - 7/20/05 - 7/21/05 - 7/22/05 - 7/23/05 - 7/24/05 - 7/25/05 - 7/26/05 - 7/27/05 - 7/28/05 - 7/29/05 - 7/30/05 - 7/31/05 - 8/1/05 - 8/2/05 - 8/3/05 - 8/4/05 - 8/5/05 - 8/6/05 - 8/7/05 - 8/8/05 - 8/9/05 - 8/10/05 - 8/11/05 - 8/12/05 - 8/13/05 - 8/14/05 - 8/15/05 - 8/16/05 - 8/17/05 - 8/18/05 - 8/19/05 - 8/20/05 - 8/21/05 - 8/22/05 - 8/23/05 - 8/24/05 - 8/25/05 - 8/26/05 - 8/27/05 - 8/28/05 - 8/29/05 - 8/30/05 - 8/31/05 - 9/1/05 - 9/2/05 - 9/3/05 - 9/4/05 - 9/5/05 - 9/6/05 - 9/7/05 - 9/8/05 - 9/9/05 - 9/10/05 - 9/11/05 - 9/12/05 - 9/13/05 - 9/14/05 - 9/15/05 - 9/16/05 - 9/17/05 - 9/18/05 - 9/19/05 - 9/20/05 - 9/21/05 - 9/22/05 - 9/23/05 - 9/24/05 - 9/25/05 - 9/26/05 - 9/27/05 - 9/28/05 - 9/29/05 - 9/30/05 - 10/1/05 - 10/2/05 - 10/3/05 - 10/4/05 - 10/5/05 - 10/6/05 - 10/7/05 - 10/8/05 - 10/9/05 - 10/10/05 - 10/11/05 - 10/12/05 - 10/13/05 - 10/14/05 - 10/15/05 - 10/16/05 - 10/17/05 - 10/18/05 - 10/19/05 - 10/20/05 - 10/21/05 - 10/22/05 - 10/23/05 - 10/24/05 - 10/25/05 - 10/26/05 - 10/27/05 - 10/28/05 - 10/29/05 - 10/30/05 - 10/31/05 - 11/1/05 - 11/2/05 - 11/3/05 - 11/4/05 - 11/5/05 - 11/6/05 - 11/7/05 - 11/8/05 - 11/9/05 - 11/10/05 - 11/11/05 - 11/12/05 - 11/13/05 - 11/14/05 - 11/15/05 - 11/16/05 - 11/17/05 - 11/18/05 - 11/19/05 - 11/20/05 - 11/21/05 - 11/22/05 - 11/23/05 - 11/24/05 - 11/25/05 - 11/26/05 - 11/27/05 - 11/28/05 - 11/29/05 - 11/30/05 - 12/1/05 - 12/2/05 - 12/3/05 - 12/4/05 - 12/5/05 - 12/6/05 - 12/7/05 - 12/8/05 - 12/9/05 - 12/10/05 - 12/11/05 - 12/12/05 - 12/13/05 - 12/14/05 - 12/15/05 - 12/16/05 - 12/17/05 - 12/18/05 - 12/19/05 - 12/20/05 - 12/21/05 - 12/22/05 - 12/23/05 - 12/24/05 - 12/25/05 - 12/26/05 - 12/27/05 - 12/28/05 - 12/29/05 - 12/30/05 - 12/31/05 - 2005

SPECIFICATIONS

2.5 TRIOBIT TRAVELER PART 14109  
 DATE 10/14/04

Model	Lot	Part	Start Date
225-011	AB 6652A	19	10/14/04
Operator	Operator	Q/P/N	Lot No
010 Standard Strand	000000	10/14/04	
Fiber	10/14/04		
Band	10/14/04		
Inner Assembly	10/14/04		
Outer Jacket	10/14/04		
Tail Tubing	10/14/04		
Powder	10/14/04		
Buffer Sleeve	10/14/04		
020 Wipe	10/14/04		
030 Outer Buffer Wipe Length	10/14/04		
040 Head End Jacket & Round Tip	10/14/04		
Underlayment	10/14/04		
050 Polish	10/14/04		
060 Assembly/Leak Test Bin Care	10/14/04		
Inner Lid	10/14/04		
Shrink Tube	10/14/04		
Bin Care Cover	10/14/04		
070 Prep Proximal Coupler	10/14/04		
Proximal Strainer	10/14/04		
Shrink Tube	10/14/04		
080 Mount Proximal Coupler	10/14/04		
Silber	10/14/04		
Fiber Socket Clamp	10/14/04		
Tail Clamp	10/14/04		
Screw 2-66x1/8 Socket Pan	10/14/04		
Prox Handle w/Fiber Protector	10/14/04		
Prox Handle w/Plastic	10/14/04		
Screw 2-69x3/16	10/14/04		
085 Oak Working Length	10/14/04		
Final Prod Oak Tag	10/14/04		
090 Pass Test	10/14/04		
100 QA Inspection	10/14/04		
110 Label & Package	10/14/04		
120 QA Inspected Package	10/14/04		
130 Release to FCN	10/14/04		
Comment	LEAVING		
Notes	Hand laser to 1.4K and 1.6K and 1.8K and 2.0K and 2.2K and 2.4K and 2.6K and 2.8K and 3.0K and 3.2K and 3.4K and 3.6K and 3.8K and 4.0K and 4.2K and 4.4K and 4.6K and 4.8K and 5.0K and 5.2K and 5.4K and 5.6K and 5.8K and 6.0K and 6.2K and 6.4K and 6.6K and 6.8K and 7.0K and 7.2K and 7.4K and 7.6K and 7.8K and 8.0K and 8.2K and 8.4K and 8.6K and 8.8K and 9.0K and 9.2K and 9.4K and 9.6K and 9.8K and 10.0K		





2 of 2

Model	Part Description	Operator	Date	SP/N	Lot No
225-011	AB 6652 A	OX	10/30		
010	Clutch Bands (Pair)	David	10/13/04	3650-1156	0406152
020	Wick	David	10/13/04	3650-1137	0408085
030	Pat Epo Pack 353ND	David	10/13/04	3650-1134	0408118
040	Heat Band Jacket & Rain Trip	David	10/13/04	3800-0520	0408169
050	Underlayment	David	10/13/04	3200-0622	0408102
060	Assmble/Leak Test Blirgats	David	10/13/04	1600-0005	0408091
070	Prox. Stand	David	10/15/04	2650-0074	0408091
080	Moist Prox. Stand	David	10/15/04	1600-0109	0408001
090	Prox. Stand	David	10/15/04	3300-0588	0408104
100	Prox. Stand	David	10/15/04	3650-1028	0408083
110	Prox. Stand	David	10/15/04	2800-0045	0408014
120	Prox. Stand	David	10/15/04	3650-1024	0408502
130	Prox. Stand	David	10/15/04	1600-0057	0408084
140	Prox. Stand	David	10/15/04	3650-0866	0408084
150	Prox. Stand	David	10/15/04	2800-0045	0408084
160	Prox. Stand	David	10/15/04	1600-0109	0408084
170	Prox. Stand	David	10/15/04	3650-1024	0408084
180	Prox. Stand	David	10/15/04	3650-1024	0408084
190	Prox. Stand	David	10/15/04	3650-1024	0408084
200	Prox. Stand	David	10/15/04	3650-1024	0408084
210	Prox. Stand	David	10/15/04	3650-1024	0408084
220	Prox. Stand	David	10/15/04	3650-1024	0408084
230	Prox. Stand	David	10/15/04	3650-1024	0408084
240	Prox. Stand	David	10/15/04	3650-1024	0408084
250	Prox. Stand	David	10/15/04	3650-1024	0408084
260	Prox. Stand	David	10/15/04	3650-1024	0408084
270	Prox. Stand	David	10/15/04	3650-1024	0408084
280	Prox. Stand	David	10/15/04	3650-1024	0408084
290	Prox. Stand	David	10/15/04	3650-1024	0408084
300	Prox. Stand	David	10/15/04	3650-1024	0408084
310	Prox. Stand	David	10/15/04	3650-1024	0408084
320	Prox. Stand	David	10/15/04	3650-1024	0408084
330	Prox. Stand	David	10/15/04	3650-1024	0408084
340	Prox. Stand	David	10/15/04	3650-1024	0408084
350	Prox. Stand	David	10/15/04	3650-1024	0408084
360	Prox. Stand	David	10/15/04	3650-1024	0408084
370	Prox. Stand	David	10/15/04	3650-1024	0408084
380	Prox. Stand	David	10/15/04	3650-1024	0408084
390	Prox. Stand	David	10/15/04	3650-1024	0408084
400	Prox. Stand	David	10/15/04	3650-1024	0408084
410	Prox. Stand	David	10/15/04	3650-1024	0408084
420	Prox. Stand	David	10/15/04	3650-1024	0408084
430	Prox. Stand	David	10/15/04	3650-1024	0408084
440	Prox. Stand	David	10/15/04	3650-1024	0408084
450	Prox. Stand	David	10/15/04	3650-1024	0408084
460	Prox. Stand	David	10/15/04	3650-1024	0408084
470	Prox. Stand	David	10/15/04	3650-1024	0408084
480	Prox. Stand	David	10/15/04	3650-1024	0408084
490	Prox. Stand	David	10/15/04	3650-1024	0408084
500	Prox. Stand	David	10/15/04	3650-1024	0408084
510	Prox. Stand	David	10/15/04	3650-1024	0408084
520	Prox. Stand	David	10/15/04	3650-1024	0408084
530	Prox. Stand	David	10/15/04	3650-1024	0408084
540	Prox. Stand	David	10/15/04	3650-1024	0408084
550	Prox. Stand	David	10/15/04	3650-1024	0408084
560	Prox. Stand	David	10/15/04	3650-1024	0408084
570	Prox. Stand	David	10/15/04	3650-1024	0408084
580	Prox. Stand	David	10/15/04	3650-1024	0408084
590	Prox. Stand	David	10/15/04	3650-1024	0408084
600	Prox. Stand	David	10/15/04	3650-1024	0408084
610	Prox. Stand	David	10/15/04	3650-1024	0408084
620	Prox. Stand	David	10/15/04	3650-1024	0408084
630	Prox. Stand	David	10/15/04	3650-1024	0408084
640	Prox. Stand	David	10/15/04	3650-1024	0408084
650	Prox. Stand	David	10/15/04	3650-1024	0408084
660	Prox. Stand	David	10/15/04	3650-1024	0408084
670	Prox. Stand	David	10/15/04	3650-1024	0408084
680	Prox. Stand	David	10/15/04	3650-1024	0408084
690	Prox. Stand	David	10/15/04	3650-1024	0408084
700	Prox. Stand	David	10/15/04	3650-1024	0408084
710	Prox. Stand	David	10/15/04	3650-1024	0408084
720	Prox. Stand	David	10/15/04	3650-1024	0408084
730	Prox. Stand	David	10/15/04	3650-1024	0408084
740	Prox. Stand	David	10/15/04	3650-1024	0408084
750	Prox. Stand	David	10/15/04	3650-1024	0408084
760	Prox. Stand	David	10/15/04	3650-1024	0408084
770	Prox. Stand	David	10/15/04	3650-1024	0408084
780	Prox. Stand	David	10/15/04	3650-1024	0408084
790	Prox. Stand	David	10/15/04	3650-1024	0408084
800	Prox. Stand	David	10/15/04	3650-1024	0408084
810	Prox. Stand	David	10/15/04	3650-1024	0408084
820	Prox. Stand	David	10/15/04	3650-1024	0408084
830	Prox. Stand	David	10/15/04	3650-1024	0408084
840	Prox. Stand	David	10/15/04	3650-1024	0408084
850	Prox. Stand	David	10/15/04	3650-1024	0408084
860	Prox. Stand	David	10/15/04	3650-1024	0408084
870	Prox. Stand	David	10/15/04	3650-1024	0408084
880	Prox. Stand	David	10/15/04	3650-1024	0408084
890	Prox. Stand	David	10/15/04	3650-1024	0408084
900	Prox. Stand	David	10/15/04	3650-1024	0408084
910	Prox. Stand	David	10/15/04	3650-1024	0408084
920	Prox. Stand	David	10/15/04	3650-1024	0408084
930	Prox. Stand	David	10/15/04	3650-1024	0408084
940	Prox. Stand	David	10/15/04	3650-1024	0408084
950	Prox. Stand	David	10/15/04	3650-1024	0408084
960	Prox. Stand	David	10/15/04	3650-1024	0408084
970	Prox. Stand	David	10/15/04	3650-1024	0408084
980	Prox. Stand	David	10/15/04	3650-1024	0408084
990	Prox. Stand	David	10/15/04	3650-1024	0408084
1000	Prox. Stand	David	10/15/04	3650-1024	0408084

2-11-84

SPECTRANETICS

Model	225-011	Order	AB 6652-A	Part	28	Serial Date	10/5/84
Operation/Part Description	Operator	Date	S/P/N	Lot No.	Part No.	Lot No.	Part No.
010. Still Hand Strand	G	10/15/84					
011. Band			0660-1166		0408152		
012. Inner Assembly			0660-1167		0408153		
013. Outer Jacket			0660-1167		0408154		040830
014. Call Round			0660-0540		0408100		
015. Powder			0660-0542		0408102		
016. Remot. Sleeve			1604-0066		03010511		
020. Wick	D	10/15/84	1600-0074		0409081		
021. 2-Part Epoxy for 363ND			1600-0109		04083001		
030. Cut Tip Vert. Wick Length	D	10/15/84					
040. Heat Blend Jacket & Round Tip	W	10/15/84					
041. Underpayment			0300-0660		0408104		
050. Polish	G	11/16/84					
060. Assemble/Leak Test Bifurcate	S	11/19/84					
061. Shrink Tube			0660-1028		0408103		
062. Bifurcate Cover			2800-00-0882		0408103		
063. Loc. 464			0660-1027		0408101		
070. Rem. Proximal Coupler	G	11/19/84			0408104		
071. Prox. Strain Relief			0660-0363		0408107		
072. Shrink Tube 178			2800-00-0882		0408104		
073. 2-Part Epoxy for 363ND			1600-0109		0408301		
080. Mount Proximal Coupler	G	11/19/84					
081. Slide			0660-1221		0409100		
082. Fiber Foot Clamp			0660-1220		0409101		
083. Saw 2-56 X 1/8 Slotted Pan			0660-1097		0409102		
084. Prox. Handle w/Fiber Protector			2825-01458		0409103		0409105
085. Prox. Handle w/Pins			0660-10280		0409104		0409109
086. Saw 2-56 X 3/16			0660-10281		0409107		
087. Opt. Working Length			2825-01458		0409104		0409105
088. Fiber Foot Clamp			1600-0206		0409106		
090. Resin Resk			0660-1168				
100. QA Inspection							
110. Label/Package							
120. QA Inspect Package							
130. Release for FC			066-Allocated				

Comments

MA 110513

1/5/84 Panel for 714

1/6/84 Panel for 714

1/7/84 Panel for 714

1/8/84 Panel for 714

1/9/84 Panel for 714

1/10/84 Panel for 714

1/11/84 Panel for 714

1/12/84 Panel for 714

1/13/84 Panel for 714

1/14/84 Panel for 714

1/15/84 Panel for 714

1/16/84 Panel for 714

1/17/84 Panel for 714

1/18/84 Panel for 714

1/19/84 Panel for 714

1/20/84 Panel for 714

1/21/84 Panel for 714

1/22/84 Panel for 714

1/23/84 Panel for 714

1/24/84 Panel for 714

1/25/84 Panel for 714

1/26/84 Panel for 714

1/27/84 Panel for 714

1/28/84 Panel for 714

1/29/84 Panel for 714

1/30/84 Panel for 714





SPECTRANETICS

251 TUBO TRAVELER

*5.7 inches*

Model	Lot	Part No	Part Name	Part No	Part Name
225-011	AE 6652 A	26			
Operation / Part Description	Operator	Date	Part No	Part Name	Part No
010 Still Head Stand	<i>W. J. ...</i>	<i>10/15/01</i>			
Fiber			3660-1166	04041652	
Band			3660-1137	04081085	
Inner Assembly			3660-1184	04081085	
Outer Jacket			3300-0642	04081085	
Trailing Cable			3300-0642	04081085	
Powder			1600-0006	04081085	
Remain Sleeve			2800-0077	04081085	
020 WAK	<i>W. J. ...</i>	<i>10/15/01</i>			
2 Part Epoxytek 353ND			1600-0109	04081085	
030 Out Tip Velocity Wick Length	<i>W. J. ...</i>	<i>10/15/01</i>			
040 Heat Blend Jacket & Round Tip	<i>W. J. ...</i>	<i>10/15/01</i>			
Underlaymen			3300-0642	04081085	
050 Polish	<i>W. J. ...</i>	<i>10/15/01</i>			
060 Assembly Leak Test Bifurcate	<i>W. J. ...</i>	<i>10/15/01</i>			
Inner Bag			3660-1028	04081085	
Shrink Tube			2800-0045	04081085	
Bifurcate Cover			0660-1027	04081085	
Route 454			1600-0057	04081085	
070 Rep Proximal Coupler	<i>W. J. ...</i>	<i>10/15/01</i>			
Prox Strain Relief			3660-0655	04081085	
Shrink Tube W/			2800-0077	04081085	
2 Part Epoxytek 353ND			1600-0109	04081085	
080 Mount Proximal Coupler	<i>W. J. ...</i>	<i>10/15/01</i>			
Slider			3660-1212	04081085	
Fiber Foul Solvent			083-01220	04081085	
Trailer Clamp			0660-1097	04081085	
Screw 2-56 x 1/8 Slotted Pan			2825-0258	04081085	
Prox Handle w/ Fiber Protector			0650-0230	04081085	
Prox Handle w/ Pins			0650-0231	04081085	
Screw 2-56 x 3/16			2825-0257	04081085	
086 Out Working Length	<i>W. J. ...</i>	<i>10/15/01</i>			
Free Fluid Coating			1600-0203	04081085	
090 Base Test	<i>W. J. ...</i>	<i>10/15/01</i>			
100 QA Inspection	<i>W. J. ...</i>	<i>10/15/01</i>			
110 Label Package	<i>W. J. ...</i>	<i>10/15/01</i>			
120 QA Inspection Package	<i>W. J. ...</i>	<i>10/15/01</i>			
130 Release to Qty			565 Attached		
Comments	<p><i>1. 251 TUBO TRAVELER</i></p> <p><i>2. 251 TUBO TRAVELER</i></p> <p><i>3. 251 TUBO TRAVELER</i></p> <p><i>4. 251 TUBO TRAVELER</i></p> <p><i>5. 251 TUBO TRAVELER</i></p> <p><i>6. 251 TUBO TRAVELER</i></p> <p><i>7. 251 TUBO TRAVELER</i></p> <p><i>8. 251 TUBO TRAVELER</i></p> <p><i>9. 251 TUBO TRAVELER</i></p> <p><i>10. 251 TUBO TRAVELER</i></p> <p><i>11. 251 TUBO TRAVELER</i></p> <p><i>12. 251 TUBO TRAVELER</i></p> <p><i>13. 251 TUBO TRAVELER</i></p> <p><i>14. 251 TUBO TRAVELER</i></p> <p><i>15. 251 TUBO TRAVELER</i></p> <p><i>16. 251 TUBO TRAVELER</i></p> <p><i>17. 251 TUBO TRAVELER</i></p> <p><i>18. 251 TUBO TRAVELER</i></p> <p><i>19. 251 TUBO TRAVELER</i></p> <p><i>20. 251 TUBO TRAVELER</i></p> <p><i>21. 251 TUBO TRAVELER</i></p> <p><i>22. 251 TUBO TRAVELER</i></p> <p><i>23. 251 TUBO TRAVELER</i></p> <p><i>24. 251 TUBO TRAVELER</i></p> <p><i>25. 251 TUBO TRAVELER</i></p> <p><i>26. 251 TUBO TRAVELER</i></p> <p><i>27. 251 TUBO TRAVELER</i></p> <p><i>28. 251 TUBO TRAVELER</i></p> <p><i>29. 251 TUBO TRAVELER</i></p> <p><i>30. 251 TUBO TRAVELER</i></p> <p><i>31. 251 TUBO TRAVELER</i></p> <p><i>32. 251 TUBO TRAVELER</i></p> <p><i>33. 251 TUBO TRAVELER</i></p> <p><i>34. 251 TUBO TRAVELER</i></p> <p><i>35. 251 TUBO TRAVELER</i></p> <p><i>36. 251 TUBO TRAVELER</i></p> <p><i>37. 251 TUBO TRAVELER</i></p> <p><i>38. 251 TUBO TRAVELER</i></p> <p><i>39. 251 TUBO TRAVELER</i></p> <p><i>40. 251 TUBO TRAVELER</i></p> <p><i>41. 251 TUBO TRAVELER</i></p> <p><i>42. 251 TUBO TRAVELER</i></p> <p><i>43. 251 TUBO TRAVELER</i></p> <p><i>44. 251 TUBO TRAVELER</i></p> <p><i>45. 251 TUBO TRAVELER</i></p> <p><i>46. 251 TUBO TRAVELER</i></p> <p><i>47. 251 TUBO TRAVELER</i></p> <p><i>48. 251 TUBO TRAVELER</i></p> <p><i>49. 251 TUBO TRAVELER</i></p> <p><i>50. 251 TUBO TRAVELER</i></p> <p><i>51. 251 TUBO TRAVELER</i></p> <p><i>52. 251 TUBO TRAVELER</i></p> <p><i>53. 251 TUBO TRAVELER</i></p> <p><i>54. 251 TUBO TRAVELER</i></p> <p><i>55. 251 TUBO TRAVELER</i></p> <p><i>56. 251 TUBO TRAVELER</i></p> <p><i>57. 251 TUBO TRAVELER</i></p> <p><i>58. 251 TUBO TRAVELER</i></p> <p><i>59. 251 TUBO TRAVELER</i></p> <p><i>60. 251 TUBO TRAVELER</i></p> <p><i>61. 251 TUBO TRAVELER</i></p> <p><i>62. 251 TUBO TRAVELER</i></p> <p><i>63. 251 TUBO TRAVELER</i></p> <p><i>64. 251 TUBO TRAVELER</i></p> <p><i>65. 251 TUBO TRAVELER</i></p> <p><i>66. 251 TUBO TRAVELER</i></p> <p><i>67. 251 TUBO TRAVELER</i></p> <p><i>68. 251 TUBO TRAVELER</i></p> <p><i>69. 251 TUBO TRAVELER</i></p> <p><i>70. 251 TUBO TRAVELER</i></p> <p><i>71. 251 TUBO TRAVELER</i></p> <p><i>72. 251 TUBO TRAVELER</i></p> <p><i>73. 251 TUBO TRAVELER</i></p> <p><i>74. 251 TUBO TRAVELER</i></p> <p><i>75. 251 TUBO TRAVELER</i></p> <p><i>76. 251 TUBO TRAVELER</i></p> <p><i>77. 251 TUBO TRAVELER</i></p> <p><i>78. 251 TUBO TRAVELER</i></p> <p><i>79. 251 TUBO TRAVELER</i></p> <p><i>80. 251 TUBO TRAVELER</i></p> <p><i>81. 251 TUBO TRAVELER</i></p> <p><i>82. 251 TUBO TRAVELER</i></p> <p><i>83. 251 TUBO TRAVELER</i></p> <p><i>84. 251 TUBO TRAVELER</i></p> <p><i>85. 251 TUBO TRAVELER</i></p> <p><i>86. 251 TUBO TRAVELER</i></p> <p><i>87. 251 TUBO TRAVELER</i></p> <p><i>88. 251 TUBO TRAVELER</i></p> <p><i>89. 251 TUBO TRAVELER</i></p> <p><i>90. 251 TUBO TRAVELER</i></p> <p><i>91. 251 TUBO TRAVELER</i></p> <p><i>92. 251 TUBO TRAVELER</i></p> <p><i>93. 251 TUBO TRAVELER</i></p> <p><i>94. 251 TUBO TRAVELER</i></p> <p><i>95. 251 TUBO TRAVELER</i></p> <p><i>96. 251 TUBO TRAVELER</i></p> <p><i>97. 251 TUBO TRAVELER</i></p> <p><i>98. 251 TUBO TRAVELER</i></p> <p><i>99. 251 TUBO TRAVELER</i></p> <p><i>100. 251 TUBO TRAVELER</i></p>				



2-9-1994  
 7/15/01

PEC TRANETICS 225-011 3725 TRIBB TRAVELER

Model	Lot#	Part#	Start Date
225-011	AB 6652A	29	10/15/01
Operator/Part Description	Operator	DATE	SP/N
010 Stiffen Stand	J Douly	10/16/01	
Fiber	J Douly		3650-11661
Band			3650-1167
Holder/Assembly			3650-116
Optic Packet			3600-0540
Tail Tubing			3300-0542
Powder			15010005
Perma Sleeve			2800-0074
020 Wbr	J Douly	10/16/01	
2 Part Epoxy Tek 359ND	J Douly		1600-0109
030 Curable Vert Wbr Length	J Douly	10/15/01	
040 Heat Bend Jacket & Round Tip	J Douly	11/15/01	
Underlayment			3500-0666
060 Roll 15	J Douly	11/16/01	
080 Assembly/Leak Test Bifurcate	J Douly	11/17/01	
Shrink Tubey			3650-1108
Bifurcate Cover			2800-09
Coil 454			3650-1027
070 Prop Proximal Coupler	J Douly	11/19/01	
Prox Strain Relief			3650-0855
Shrink Tubey			2800-09
2 Part Epoxy Tek 359ND			1600-0109
60 Mount Proximal Coupler	J Douly	11/19/01	
Slide			3650-124
Break Foot Clamp			3650-129
Clamp			3650-1097
Screw 2.56 x 1/8 Slotted Pan			2826-0258
Prox Handle w/Fiber Protector			3650-0210
Prox Handle w/HIS			3650-028
Screw 2.56 x 3/16			2826-046
080 Coax Working Length	J Douly	11/30/01	
Slide Knob On Lid			1600-0206
090 Base Test	J Douly	11/30/01	
100 QA Inspection	J Douly	12/5/01	
110 Label Package	J Douly	12/5/01	
120 QA Inspect Package	J Douly	12/5/01	
130 Release to HCL			

Comments

1. See faced base 764 (see 10/16/01)  
 2. QA inspection wear (see 12/5/01)  
 3. QA inspection wear (see 12/5/01)  
 4. QA inspection wear (see 12/5/01)  
 5. QA inspection wear (see 12/5/01)  
 6. QA inspection wear (see 12/5/01)  
 7. QA inspection wear (see 12/5/01)  
 8. QA inspection wear (see 12/5/01)  
 9. QA inspection wear (see 12/5/01)  
 10. QA inspection wear (see 12/5/01)

775































































EXHIBIT 8

Revision of proposed IFU 7030-0153 Peripheral  
CLiRpath™ Excimer Laser Catheters

## CLiRpath™ Excimer Laser Catheters

Cool Laser Revascularization for Peripheral Artery Therapy  
Extreme® (OTW) and Vitesse® (RX) Catheter Models

### Instructions For Use

#### Table of Contents

1. DESCRIPTION.....	1
2. INDICATIONS FOR USE.....	2
3. CONTRAINDICATIONS.....	2
4. WARNINGS.....	2
5. PRECAUTIONS.....	2
6. POTENTIAL ADVERSE EVENTS .....	2
7. CLINICAL STUDIES.....	3
8. INDIVIDUALIZATION OF TREATMENT.....	3
9. OPERATOR'S MANUAL .....	4
10. HOW SUPPLIED.....	4
10.1 STERILIZATION .....	4
10.2 INSPECTION PRIOR TO USE .....	4
10.3 PROCEDURE SET UP .....	4
10.4 COMPATIBILITY .....	4
11. DIRECTIONS FOR USE.....	4
12. COMPANY INFORMATION.....	6

For **Extreme®**, over the wire (OTW) catheters, a Luer adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the appropriate sized guidewire (0.014", 0.016", 0.018", 0.025", and 0.035") see inset below.

For **Vitesse®**, rapid exchange (RX) catheters, the guidewire lumen is formed only through the last 9 cm of the distal tip, which has direct patient contact, and is concentric with the fiber array; see inset below.

For **Vitesse®-E**, rapid exchange (RX) eccentric catheters, the laser catheter consists of eccentrically aligned optical fibers and a stainless steel torque device encased within a polyester shaft. There are two major portions of the laser catheter shaft, the proximal portion which terminates at the laser connector, and the distal portion which terminates at the tip having direct patient contact. The torque device extends from the torque handle, located at the y-adapter, through the entire 140 cm of the distal portion of the catheter, and terminates in the distal tip. There is a mechanism within the torque handle which limits the turns to five full rotations in each direction. The torque handle also has an indicator displaying its range of motion. The laser catheter is packaged with the indicator in the center of its range (see inset below). The torque response is 6:1; six turns of the torque handle result in one 360° turn of the distal tip. A radiopaque marker band with radiolucent window is located on the distal tip of the laser catheter to aid

#### Description

Spectranetics CLiRpath™ excimer laser catheters are percutaneous intravascular devices constructed of multiple optical fibers arranged around a guidewire lumen.

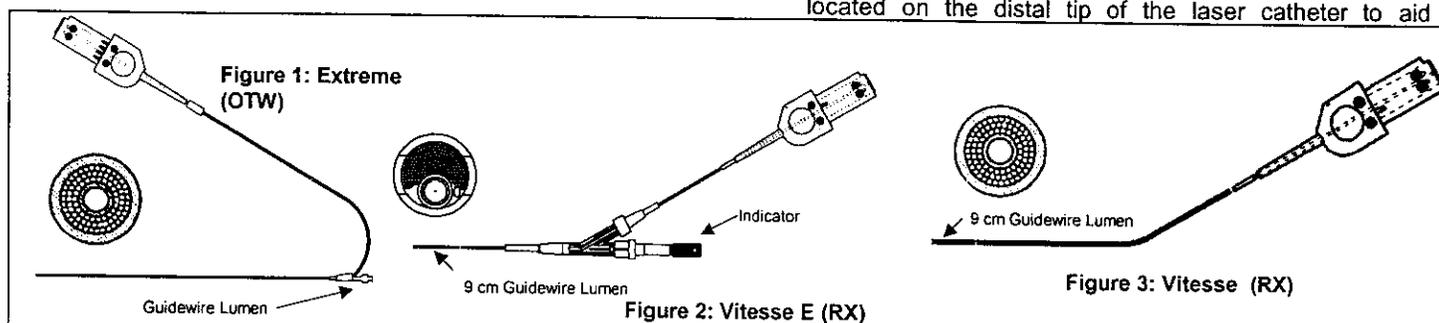


Table 1.1 CLiRpath Excimer Laser Catheter Models

Device OD Outer Diameter (mm)	Model Number	Max. Guidewire Lumen (In.)	Max. Tip Outside Diameter (In.)	Min. Tip Inside Diameter (In.)	Max. Shaft Diameter (In.)	Min Tail Tube Length (cm)	Min Working Length (cm)
<i>Extreme (OTW) Catheter Specifications</i>							
0.9 mm	110-001	0.014	0.038	0.0155	0.047	183	130
0.9 mm X80	110-002	0.014	0.038	0.0155	0.047	183	130
1.4 mm	114-001	0.014	0.056	0.017	0.056	183	131
1.7 mm	117-002	0.018	0.064	0.021	0.065	183	131
2.0 mm	120-001	0.018	0.077	0.021	0.076	183	131
2.0 mm II	220-006	0.018	0.0775	0.026	0.083	168	131
2.2 mm	222-005	0.035	0.088	0.037	0.089	168	120
2.3 mm II	223-001	0.035	0.092	0.039	0.094	168	120
2.5 mm	225-004	0.035	0.1	0.037	0.098	168	100
2.5 mm II	225-010	0.035	0.099	0.039	0.101	168	100
2.5 mm Turbo	225-011	0.018	0.1004	0.025	0.102	168	110

Device OD Outer Diameter (mm)	Model Number	Max. Guidewire Lumen (In.)	Max. Tip Outside Diameter (In.)	Min. Tip Inside Diameter (In.)	Max. Shaft Diameter (In.)	Min Tail Tube Length (cm)	Min Working Length (cm)
<i>Vitesse (RX) Catheter Specifications</i>							
0.9 mm	110-003	0.014	0.038	0.0155	0.049	183	131
0.9 mm X80	110-004	0.014	0.038	0.0155	0.049	183	131
1.4 mm	114-009	0.014	0.057	0.0175	0.062	183	131
1.7 mm	117-016	0.014	0.0685	0.0175	0.072	183	131
1.7 mm E	117-205	0.014	0.0685	0.0175	0.072	183	129
2.0 mm E	120-008	0.018	0.0785	0.0205	0.084	183	129
2.0 mm	120-009	0.014	0.08	0.0175	0.084	183	131

localization within the coronary vasculature in conjunction with fluoroscopy.

### Mechanism of Action for CLiRpath Catheters

The multifiber laser catheters transmit ultraviolet energy from the Spectranetics CVX-300<sup>®</sup> to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photo-ablate fibrous, calcific, and atheromatous lesions, thus recanalizing diseased vessels (photo ablation is the process by which energy photons cause molecular bond disruption at the cellular level without thermal damage to surrounding tissue). The Spectranetics laser catheters have a proprietary lubricious coating to ease their trackability through arteries.

### Glossary of Special Terms

*Retrograde Fashion* = In the direction opposite to blood flow.

*Antegrade Fashion* = In the direction of blood flow.

*Baseline Angiography* = Angiographic record of blood vessels.

*Contralateral Approach* = Arterial access by a crossover approach.

## 2. Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Note: Successful step-by-step passage of guide wires does not necessarily ensure relief of critical limb ischemia. Additional procedures may be required.

### Contraindications

- No known contraindications.

## 4. Warnings

**Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.**

Spectranetics Excimer Laser Catheters require CVX-300<sup>®</sup> software versions 3.708 or 3.808 and higher.

When the laser catheter is in the body, it should be manipulated only while it is under fluoroscopic observation with radiographic equipment that provides high quality images.

The use of the CVX-300<sup>®</sup> Excimer Laser System is restricted to physicians who are trained in peripheral vascular intervention and who meet the training requirements listed below. These requirements include, but are not limited to:

1. Training of laser safety and physics.
2. Review of patient films of lesions that meet the indications for use.
3. A review of cases demonstrating the CLiRpath technique in occlusions that meet the indications for use.
4. A review of laser operation followed by a demonstration of the CVX-300<sup>®</sup> Excimer Laser System.

5. Hands on training with the CVX-300<sup>®</sup> Excimer Laser System and appropriate model.
6. A fully trained Spectranetics representative will be present to assist for a minimum of the first three cases.
7. Following the formal training session, Spectranetics will make available additional training if so requested by the physician, support personnel, the institution or Spectranetics.

## 5. Precautions

This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for **SINGLE USE ONLY** and must not be resterilized and/or reused.

Store in a cool, dry place. Protect from direct sunlight and high temperatures (*greater than 60°C or 140°F*).

The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised. Do not use catheter product if its "Use Before Date," found on package labeling, has been passed.

Before use, examine carefully all of the equipment to be used in the procedure for defects. Do not use any equipment if it is damaged.

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially biohazardous materials.

Read the Operator's Manual (7030-0035 or 7030-0068) thoroughly before operating the Excimer Laser System. Pay particular attention to the Warnings and Responsibility section of the manual which explains Notes, Cautions, and Warnings to be followed to ensure safe operation of the CVX-300<sup>®</sup>.

During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution's PTA protocol.

## 6. Adverse Events

Use of the Spectranetics CVX-300<sup>®</sup> Excimer Laser System may contribute to the following complications:

Events Observed during CLiRpath Clinical Studies (see Section 7)

Procedural Complications	Serious Adverse Events
<ul style="list-style-type: none"><li>• Spasm</li><li>• Major dissection</li><li>• Thrombus</li><li>• Distal embolization</li><li>• Perforation</li><li>• Other</li></ul>	<ul style="list-style-type: none"><li>• Death</li><li>• Reintervention</li><li>• ALI</li><li>• Major amputation</li><li>• Bypass Surgery</li><li>• Hematoma with Surgery</li></ul>

### In-Hospital Complications

- Reocclusion
- Pseudoaneurysm
- Renal failure
- Bleeding

Potential Averse Events NOT Observed during CLiRpath Clinical Studies (see Section 7)

- Nerve Injury
- AV Fistula Formation
- Endarterectomy
- Infection
- Stroke
- Myocardial Infarction
- Arrhythmia

No long term adverse effects on the arterial vessel wall, due to peripheral excimer laser recanalization, are known at this time.

7. Clinical Studies

Data presented in this IFU comprise of a subset of patients pooled from three sources of consecutively treated patients presenting with Critical Limb Ischemia (CLI), who were poor surgical candidates:

- LACI Phase 2 – a subset of patients from a prospective IDE registry conducted in 2001-2002 at 14 sites in the US and Germany. The subset includes 26 limbs (in 25 patients) treated at 7 sites from the US and Germany in which the step by step CLiRpath laser recanalization technique was utilized. In 13 of these cases, step-by-step technique was utilized *ab initio*, that is, without first attempting to cross the occlusion with a guidewire.
- LACI Belgium - a subset of a 51-patient prospective registry conducted at 6 sites in Belgium. The subset includes 9 limbs (in 9 patients) treated at 3 sites in Belgium in which the step by step CLiRpath laser recanalization technique was utilized.
- Louisiana case series – a subset drawn from 62 cases included in an on-going data compilation by a single physician group in central Louisiana, the Cardiovascular Institute of the South (CIS). This subset of patients consists of 12 limbs (in 12 patients) in which the step by step CLiRpath laser recanalization technique was utilized.

Table 7.1 Procedure Information

Locations of vascular lesions (n=205)	
SFA	138 (67%)
Popliteal	23 (11%)
Infrapopliteal	42 (20%)

Angiographic Results (n=47 limbs)	
Lesions per limb	4.4
Average lesion length	73.4 ± 7.3 (mm)
Straight line flow to foot established	37 (79%)
Stent implanted	28 (60%)
Crossing Success Overall*	37 (79%)
Crossing Success after Guidewire Attempt	24/34 (71%)
Crossing Success <i>ab initio</i> Cases	13/13 (100%)
Procedure success**	34 (72%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

\*Crossing Success data has been stratified for step-by-step cases after conventional guidewire attempts in 24 limbs, and *ab initio* in 13 limbs.

\*\*Procedure success: ≤50% final residual stenosis

Table 7.2 Complications, n=47 limbs

Procedural Complications	
Spasm	1 (2%)
Major dissection	4 (9%)
Thrombus	1 (2%)
Distal embolization	3 (6%)
Perforation	3 (6%)
Other	5 (11%)
In-Hospital Complications	
Reocclusion	1 (2%)
Pseudoaneurysm	1 (2%)
Renal failure	1 (2%)
Bleeding	1 (2%)
Infection	0 (0%)
Other	0 (0%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

Table 7.3 Cumulative Serious Adverse Events (SAEs) through 6-month follow-up, for n=47 limbs

Death	3 (6%)
MI or Stroke	0 (0%)
Reintervention	6 (13%)
ALI	1 (2%)
Major amputation	2 (4%)
Bypass Surgery	2 (4%)
Endarterectomy	0 (0%)
Hematoma with Surgery	2 (4%)
Total	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

MI = Myocardial Infarction. ALI = Acute Limb Ischemia.

Table 7.4 Outcomes by Intention-to-Treat Analysis, n=47

Crossing Success	37 (79%)
Procedure Success	34 (72%)
Limb Salvage	40 (85%)
Death, any cause	3 (6%)
Any SAE	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

8. Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the CLiRpath device.

Use of CLiRpath devices may be considered after initial conventional crossing attempts with guidewires are unsuccessful due to:

- A rounded or eccentric occlusion stump deflecting the guidewire to a subintimal passage.
- The guidewire repeatedly being deflected into a large collateral branch flush with the occlusion stump.
- Calcification obstructing completion of guidewire passage within the obstructed lumen.

Additionally, recanalization of native arteries may be considered in patients presenting with occluded bypass grafts.

Patient selection and clinical techniques should be conducted according to instructions provided in Section 2, "Indications for Use," and Section 9, "Operator's Manual."

**9. Operator's Manual**

The devices described in this document can be operated within the following energy ranges on the CVX-300®:

Table 9.1 Energy Parameters

Device O.D.	Model No.	Fluence	Repetition Rate	Laser On/Off Time
<b>Extreme (OTW) Catheters</b>				
0.9 mm	110-001	30-60	25-40	5 sec on/10 sec off
0.9 mm X/80	110-002	30-80	25-80	10 sec on/5 sec off
1.4 mm	114-001	30-60	25-40	5 sec on/10 sec off
1.7 mm	117-002	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-001	30-60	25-40	5 sec on/10 sec off
2.0 mm	220-006	30-60	25-40	10 sec on/5 sec off
2.2 mm	222-005	30-60	25-40	5 sec on/10 sec off
2.3 mm	223-001	30-60	25-40	10 sec on/5 sec off
2.5 mm	225-004	30-50	25-40	5 sec on/10 sec off
2.5 mm	225-010	30-50	25-40	10 sec on/5 sec off
2.5 mm	225-011	See note 1	25-40	Continuous On
<b>Vitesse (RX) Catheters</b>				
0.9 mm	110-003	30-60	25-40	5 sec on/10 sec off
0.9 mm X/80	110-004	30-80	25-80	10 sec on/5 sec off
1.4 mm	114-009	30-60	25-40	5 sec on/10 sec off
1.7 mm	117-016	30-60	25-40	5 sec on/10 sec off
1.7 mm E	117-205	30-60	25-40	5 sec on/10 sec off
2.0 mm E	120-008	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-009	30-60	25-40	5 sec on/10 sec off

Recommended calibration settings: 45 Fluence, 25 Hz.

Note 1: max fluence listed on box label.

**10. How Supplied**

**10.1 Sterilization**

For single use only. Do not re-sterilize and/or reuse.

The Spectranetics laser catheters are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

**10.2 Inspection Prior to Use**

Before use, visually inspect the sterile package to ensure that seals have not been broken. All equipment to be used for the procedure, including the catheter, should be examined carefully for defects. Examine the laser catheter for bends, kinks or other damage. Do not use if it is damaged.

**10.3 Procedure Set Up**

Some or all of the following additional materials, which are not included in the laser catheter package, may be required for the procedure (these are single use items only—do not re-sterilize or reuse):

- Introducer sheaths and/or femoral guiding catheter(s) in the appropriate size and configuration to select the peripheral artery and facilitate largest laser catheter to be used.
- Tuohy-Borst "y" adapter or hemostatic valve(s).
- Sterile normal saline or Lactated Ringer's solution
- Standard contrast media
- 0.014", 0.016", 0.018", 0.025", or 0.035" guidewires

**10.4 Compatibility**

The Spectranetics' excimer laser catheter is designed and intended to be used exclusively with the Spectranetics CVX-300® Laser System.

Do not use in combination with any other laser system.

**Guidewire Compatibility**

See Catheter Specification Table in Section 1.

**11. Directions for Use**

Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the laser catheter from the tray while supporting the black laser connector, also known as the proximal end, proximal coupler, or proximal connector. Please note that the proximal end of the laser catheter connects only to the CVX-300®, and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the CVX-300® and position the laser catheter in the laser system extension pole. Calibrate the laser catheter following the instructions provided in the CVX-300® Operator's Manual (7030-0035 or 7030-0068).

1. Use standard femoral puncture technique to insert a 5 Fr. to 9 Fr. (depending on the largest interventional device to be used during treatment) introducer sheath into the common femoral artery in antegrade or retrograde fashion for contralateral approaches. Heparinize intravenously using the PTA protocol for heparinization.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014", 0.016", 0.018", 0.025", or 0.035" guidewire to the peripheral occlusion via the introducer sheath or guiding catheter.
4. Size and choose the laser catheter appropriately:

Table 11.1 Recommended Sizing

Catheter Size	Proximal Vessel Diameter
0.9 mm	≥1.5 mm
0.9 mm X/80	≥2.0 mm
1.4 mm	≥2.2 mm
1.7 mm	≥2.5 mm
2.0 mm	≥3.0 mm
2.2 mm	≥3.2 mm
2.3 mm	≥3.2 mm
2.5 mm	≥3.5 mm

Note: Choosing an eccentric laser catheter may be appropriate when lesion morphology or the location and tortuosity of the occluded vessel imply eccentric ablation would assist in following the true vessel lumen. Eccentric ablation may help avoid subintimal passage in such cases.

5. This step applies only to Extreme catheter models. Inject 5-10cc of heparinized saline or Lactated Ringer's solution through the laser catheter to flush the guidewire lumen. Attach a rotating hemostatic valve to the guidewire port into the guidewire lumen (See Figure 4). Introduce the distal tip of the Spectranetics laser catheter over the selected guidewire. Under fluoroscopic control, guide the laser catheter to the lesion. The laser catheter's radiopaque band marker indicates its position relative to the lesion.

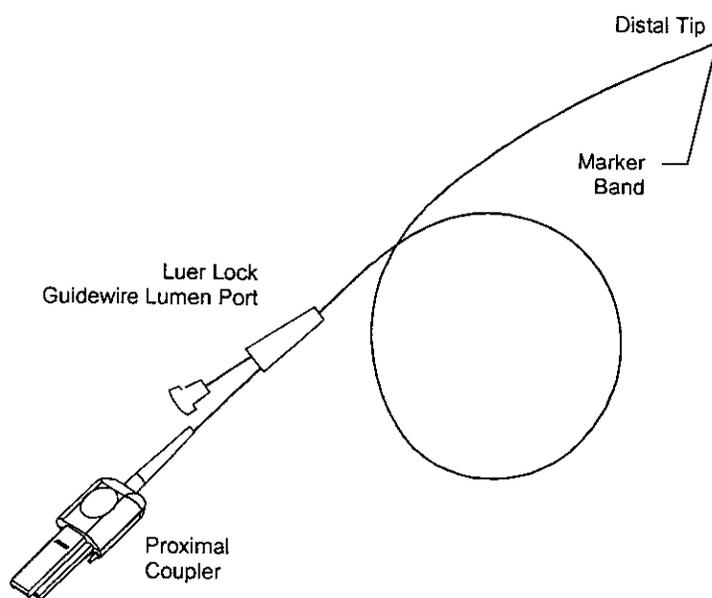


Figure 4 (not to scale)

11. Cross the last 3-5 mm of the occlusion and enter the patent distal vessel with the guidewire first, followed by the activated laser catheter over the wire.
12. Leaving the guidewire in position, pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.
13. Additional laser passes may be performed over the wire to achieve greater debulking of the lesion.

**Note**

If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter outer surface, inner lumen, and tip with heparinized saline to prevent blood from sticking. Blood remaining on the laser catheter may diminish the efficiency of the laser catheter.

If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the CVX-300®. The fluence and repetition rates can be increased in order to advance. To avoid the potential of heat build-up, the catheter must be advanced while lasing.

14. There is no need to remove the laser catheter from the patient in order to increase or decrease either the fluence or pulse repetition rate; as the laser catheter was previously calibrated. Refer to the CVX-300® Excimer Laser System Operator's Manual, 7030-0035 or 7030-0068.

**Caution**

All patients should be monitored for blood pressure and heart rate during the procedure.

15. Following laser recanalization, perform follow up angiography and balloon angioplasty if needed. Stenting may be performed as required, in instances of acute recoil, major perforation, etc.
16. Recommended pharmacology follow up to be prescribed by the physician.

**EXCIMER LASER SALINE INFUSION PROTOCOL**

**Note**

This technique requires two operators. It is recommended that the primary physician operator advance the laser catheter and operate the laser system foot pedal. A scrub assistant should manage the saline infusion control syringe and (if appropriate) depress the fluoroscopy pedal.

- A. Before the laser procedure, warm a 500cc bag of 0.9% normal saline (NaCl), or Lactated Ringer's (LR) solution, to 37°C. It is not necessary to add heparin or potassium to the saline/LR solution. Connect the bag of warmed saline/LR to a sterile intravenous line and terminate the line at a port on a triple manifold.

6. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
7. Following confirmation of the laser catheter's position in contact with the target lesion and using normal saline or Lactated Ringer's solution:
  - a. Flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors,
  - b. Flush all residual contrast media from the lasing site and vascular structures adjacent to the lasing site, prior to activating the CVX-300® laser system.
  - c. Please refer to the Saline Infusion Protocol section of these Instructions for Use and perform saline flush and infusion per the instructions.
8. Depress the footswitch, activating the CVX-300®, and **slowly**, less than 1 mm per second, advance the laser catheter 2-3 mm into the total occlusion, allowing the laser energy to remove the desired material. Release the footswitch to deactivate the CVX-300®.

**Note**

Advancing the laser catheter through moderately calcified lesions may require more pulses of laser energy than fibrous atherosclerotic tissue.

9. Advance the guidewire beyond the distal tip of the laser catheter further into the occlusion, a few millimeters, and reactivate the laser as described in Step 8 above.
10. Continue in this step-by-step manner where the guidewire and then the laser catheter are advanced and activated (mm by mm) until the catheter reaches the last 3-5 mm of the occlusion.

- B. If applicable, cannulate the ostium of the artery with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter **not** have side holes.
- C. Under fluoroscopic guidance, advance the laser catheter into contact with the lesion. If necessary, inject contrast to help position the tip of the laser catheter. If contrast appears to have become entrapped between the laser catheter tip and the lesion, the laser catheter may be retracted slightly (1-2mm) to allow antegrade flow and contrast removal while flushing the system with saline/LR. **However, before lasing, ensure that the laser catheter tip is in contact with the lesion.**
- D. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline/LR through the manifold into the control syringe.
- E. Remove the original control syringe from the manifold and replace it with a fresh 20cc luer-lock control syringe. This new 20cc control syringe should be primed with saline/LR prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20cc control syringes.)
- F. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and introducer sheath or guide catheter, with at least 20-30cc of saline/LR (several syringes of saline/LR). When this initial flushing is completed, refill the 20cc control syringe with saline/LR.
- Under fluoroscopy, confirm that the tip of the laser catheter is in contact with the lesion (advance the laser catheter if necessary), but do **not** inject contrast.
- H. When the primary operator indicates that he/she is ready to activate the laser system, the scrub assistant should turn the manifold stopcock off to pressure and inject 10cc of saline/LR as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
- I. After the injection of the initial 10cc bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3cc/second. This portion of the saline/LR infusion is to displace and/or dilute the antegrade blood flow entering the laser ablation field. **At the instant the scrub assistant slows down the injection rate, the primary operator should activate the laser system by depressing the foot pedal and begin a lasing sequence.**
- J. The lasing sequence (train) should last for 2 -10 seconds (maximum of 10 seconds).
- K. Terminate the saline/LR injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20cc of saline/LR in preparation for the next lasing sequence.
- L. Each subsequent laser train should be preceded by a bolus of saline/LR and performed with continuous saline/LR infusion as described in steps H-K.
- M. If contrast is used to assess treatment results during the course of a laser treatment, repeat steps D - G prior to reactivation of the laser system (before activating the laser as described in steps H - K).

**Note**

Depending on which approach is used, antegrade or contralateral, saline/LR can be administered through the sheath (antegrade approach) or laser catheter inner lumen (contralateral approach). When the contralateral approach is used, smaller diameter guidewires are suggested to allow adequate saline/LR infusion at the treatment site.

**12. Company Information**

The company's standard one-year product warranty and remedy are exclusive and expressly in lieu of all other warranties expressed or implied either in fact or by operation of law, statutory or otherwise, including warranties of merchant ability and fitness for use or for any particular purpose and of all other liabilities or obligations on the part of the company relating in any way to the CVX-300<sup>®</sup> Excimer Laser System, whether arising from personal injury, property damage or otherwise. The company neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System. Notwithstanding the generality of the foregoing, (a) the company shall have no liability whatsoever for special, consequential, incidental or punitive damages of any kind arising out of the sale, installation, service or use of the CVX-300<sup>®</sup> Excimer Laser System, and (b) the company's liability shall in no event exceed the original purchase price of the CVX-300<sup>®</sup> Excimer Laser System.

**Spectranetics**

Spectranetics Corporation  
96 Talamine Court  
Colorado Springs, Colorado 80907-5186  
USA  
Telephone 719-633-8333

Spectranetics International BV  
Plesmanstraat 6  
3833 LA Leusden  
The Netherlands  
Telephone 31-33-434-7050

August 15, 2005

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

SPECTRANETICS CORP.  
96 TALAMINE CT.  
COLORADO SPRINGS, CO 80907  
ATTN: ADRIAN E. ELFE

510(k) Number: K043465  
Product: 2.5 MM TURBO  
CLIRPATH EXCIMER  
LASER CATHETER,  
MODEL 225-011

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. 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 [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

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

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

Sincerely yours,

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

K043465/S2

**Spectranetics**

*we get your blood flowing*

12 August 2005

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

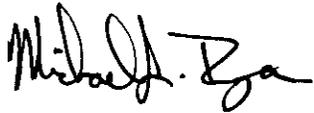
Re: 510(k), K043465, Amendment 2  
Spectranetics 2.5 mm Turbo CLiRpath Excimer Laser Catheter

Dear Dr. Cavanaugh,

Per your request, here is the Company's response to the questions that you raised in a request for additional information in a letter dated 3 August 2005. The question is repeated followed by the Company's response.

One original and two copies of this 510(k) Supplement are enclosed. We respectfully request protection provided by law for confidential commercial information or trade secrets. If further information is required, please contact Michael J. Ryan at (719) 442-2433 or Adrian E. Elfe at (719) 442-2425.

Sincerely yours,



Michael J. Ryan  
RA Manager

Coronary Artery  
Disease Therapy

Cardiac Lead  
Removal Systems

Peripheral Vascular  
Disease Therapy

CVX-300  
Excimer Technology

THE SPECTRANETICS CORPORATION  
96 Talamine Court  
Colorado Springs, CO 80907-5186  
Tel: 719-633-8333  
Customer Service: Tel: 800-231-0978  
Fax: 719-633-8791

www.spectranetics.com

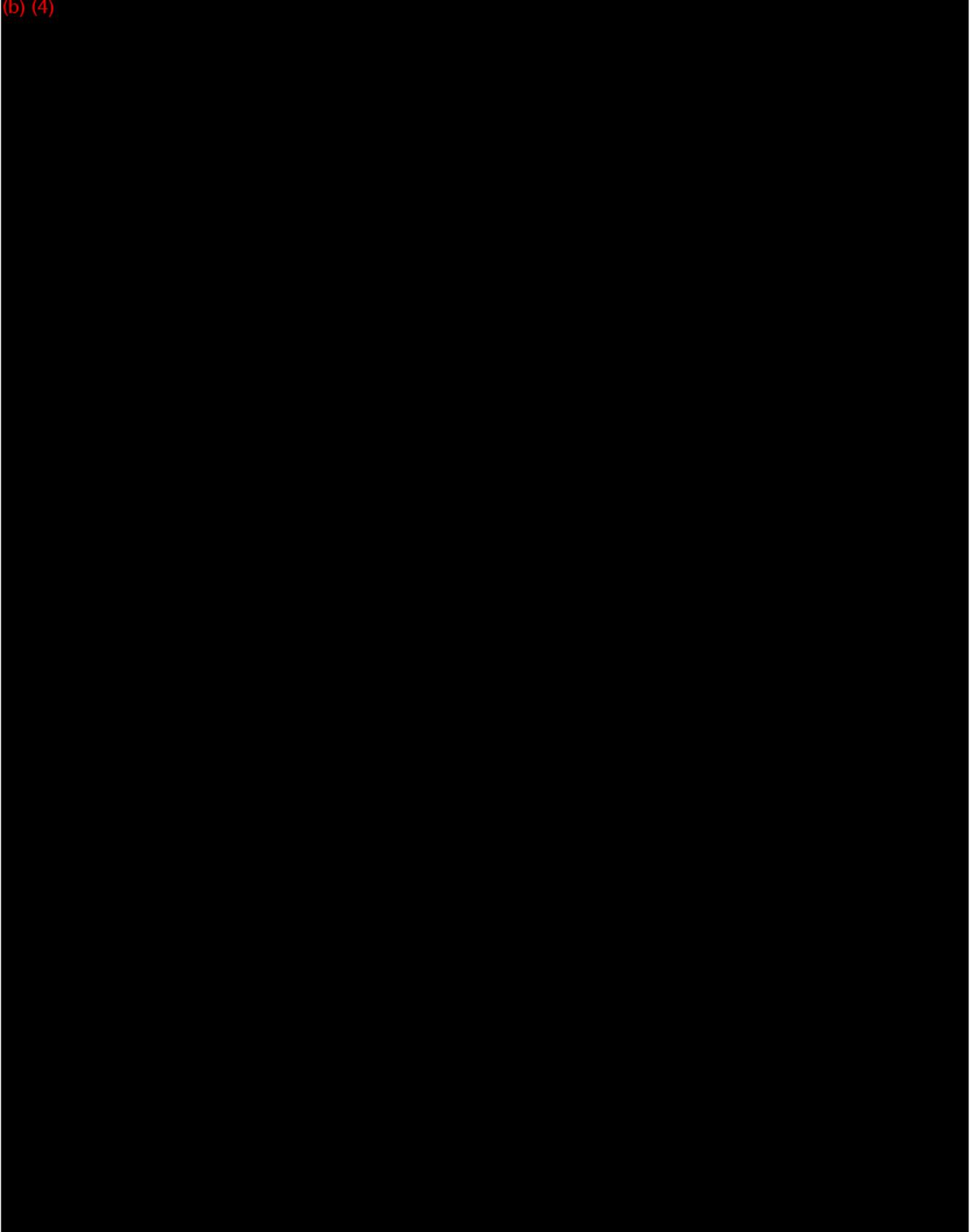
- 1 -

24

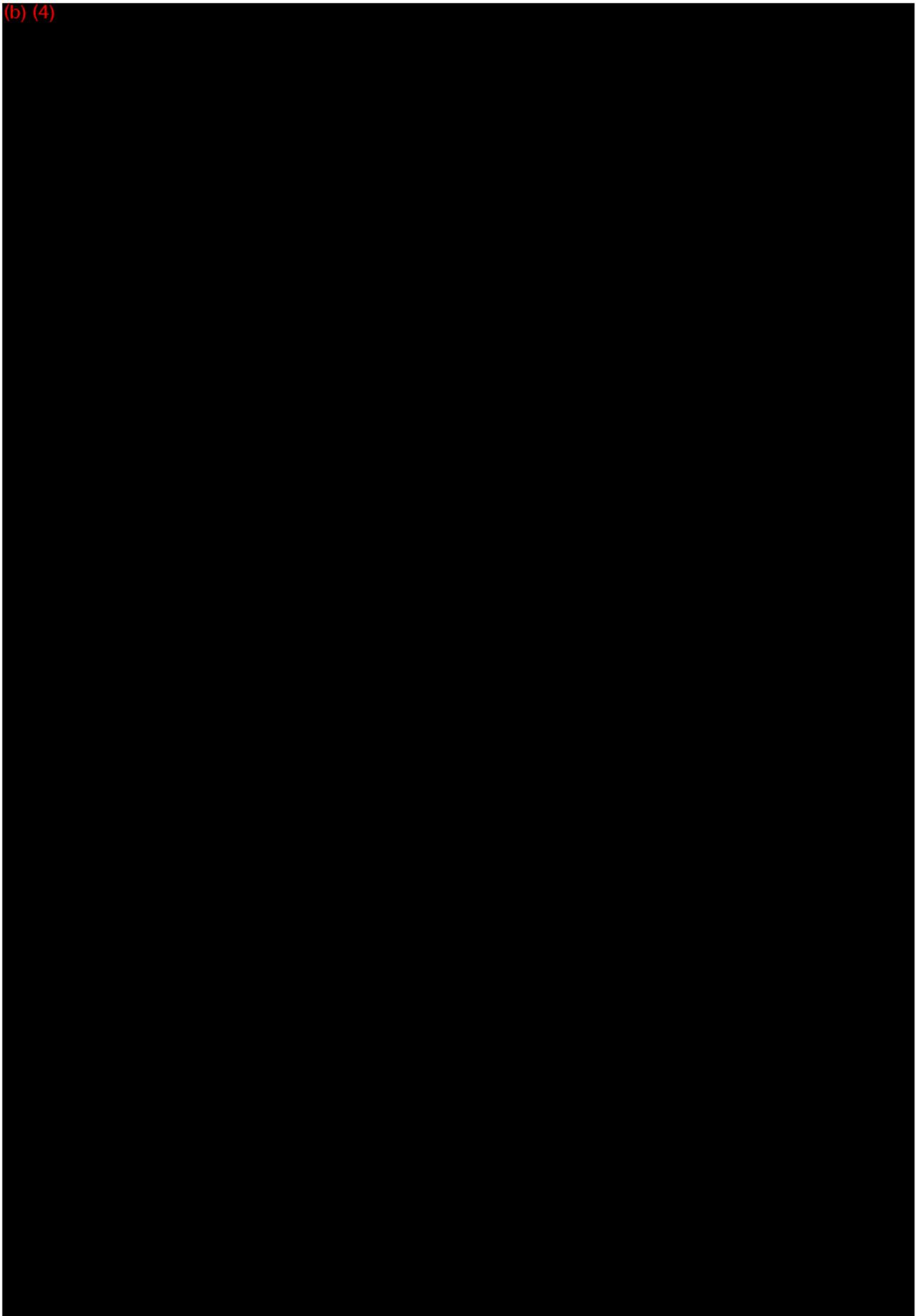
K-3

Animal Studies

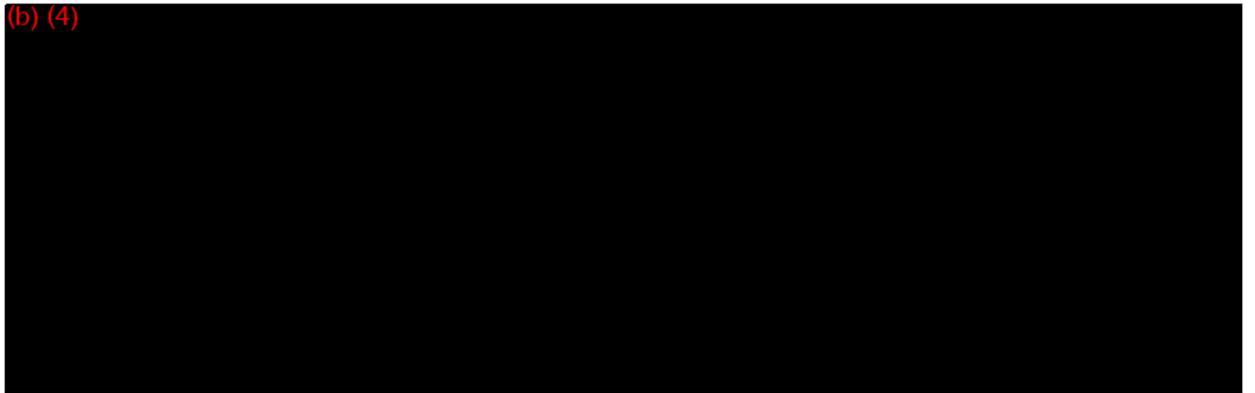
(b) (4)



(b) (4)

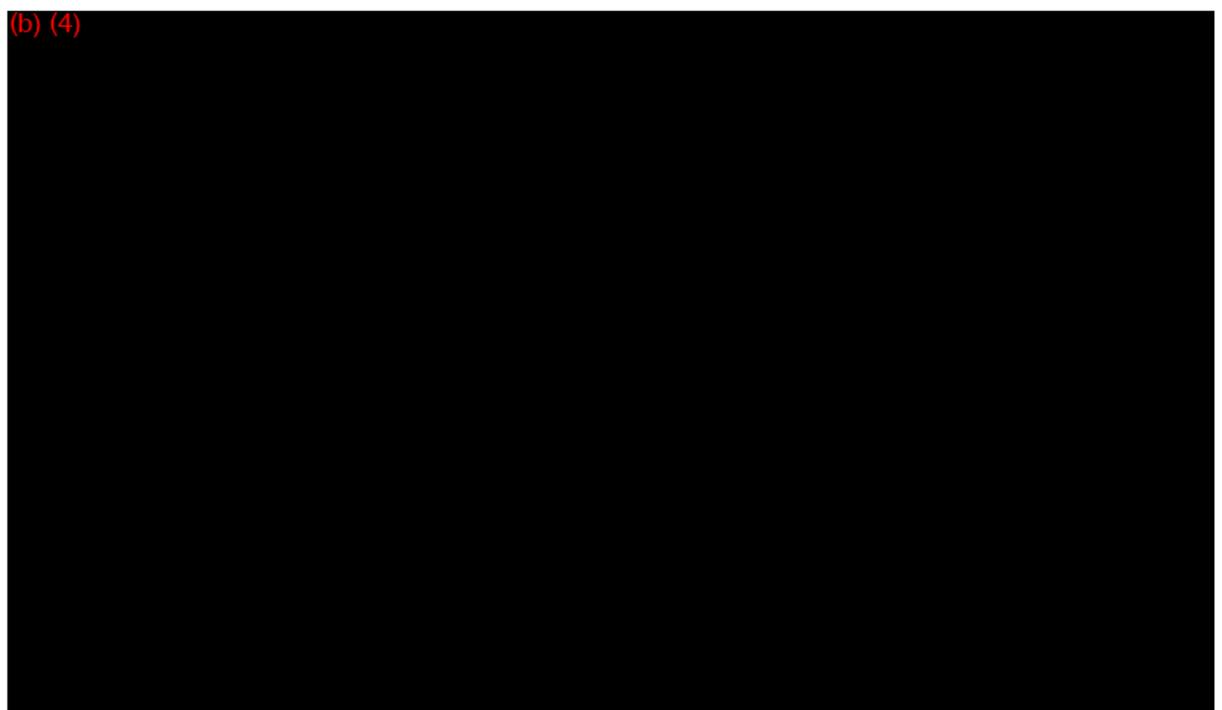


(b) (4)



Risk Analysis

(b) (4)





























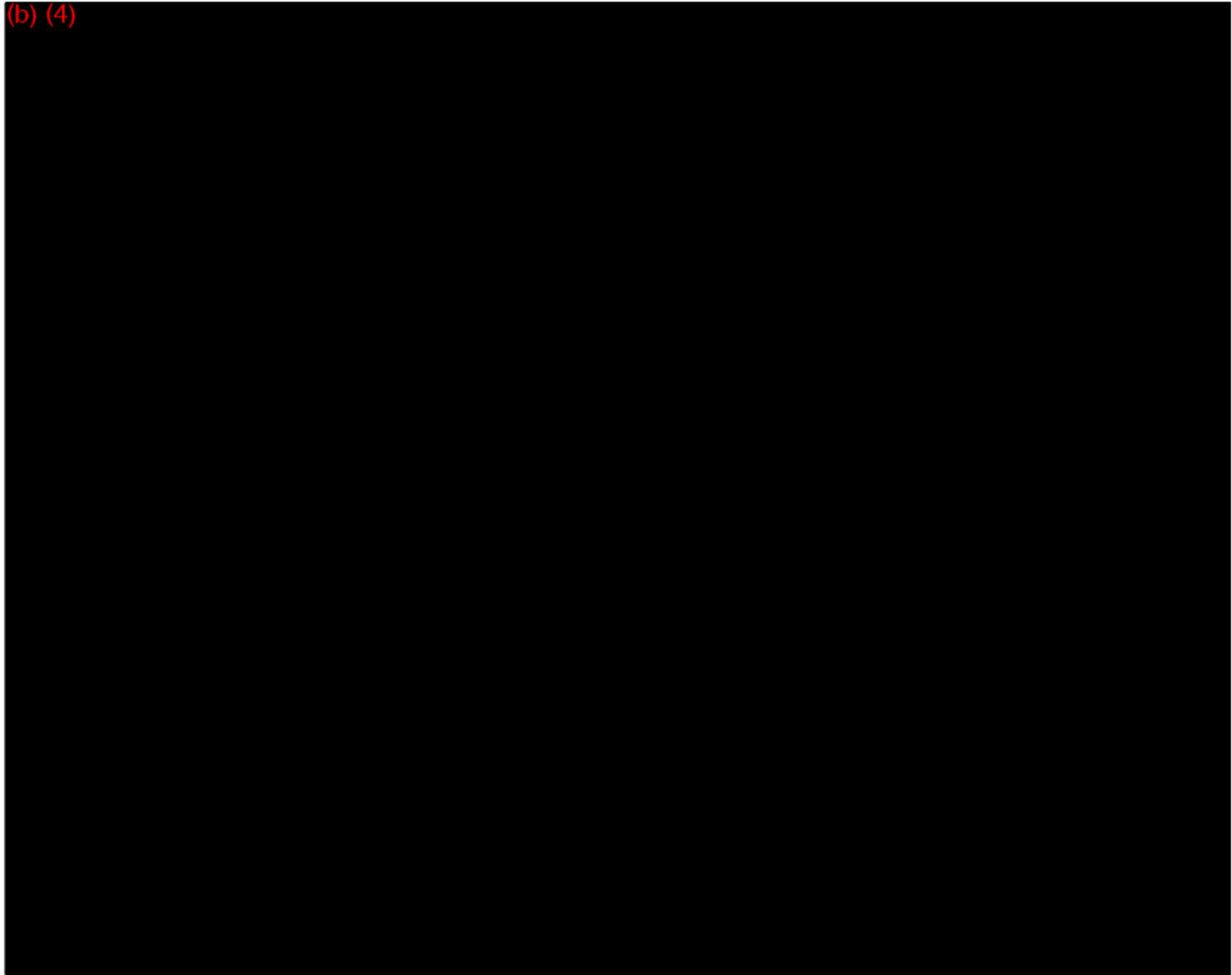






Animal Studies

(b) (4)















Bench Testing

(b) (4)

















































Bench Testing

(b) (4)

