

K061373  
510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: 15 May 2006

AUG 01 2006

510(k) number: \_\_\_\_\_

**Applicant Information:**

VNUS Medical Technologies, Inc.  
5799 Fontanoso Way  
San Jose, CA 95138

Contact Person: Carelle Karimimanesh  
Phone Number: (408) 360-7261  
Fax Number: (408) 365-8480

**Device Information:**

Classification: Class II  
Trade Name: VNUS® ClosureFAST™ Catheter  
Classification Name: Electrosurgical Device (21 CFR §878.4400)

**Equivalent Device:**

The subject device is substantially equivalent in intended use and/or method of operation to the VNUS® ClosurePlus™ Catheter (K030557).

The technological characteristics and principals of operation of the VNUS ClosureFAST catheter are substantially equivalent to the noted predicate device. Both devices rely on the delivery of RF energy to an intravascular catheter that heats a blood vessel to a specific temperature to achieve the intended use.

**Intended Use:**

The VNUS® ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

**Test Results:**

*Performance*

Results of *in vitro* testing demonstrate that the VNUS ClosureFAST catheter is substantially equivalent to the predicate device effective for its intended function.

*Biocompatibility*

The materials used in the VNUS ClosureFAST Catheters have been shown to be biocompatible.

**Summary:**

Based on the intended use, product performance, and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

VNUS Medical Technologies, Inc.  
% Carelle Karimimanesh  
Director, Regulatory Affairs  
2200 Zanker Road, Suite F  
San Jose, California 95131

AUG 01 2006

Re: K061373

Trade/Device Name: VNUS<sup>®</sup> ClosureFAST<sup>™</sup>

Regulatory Number: 21 CFR 878.4400

Regulatory Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: II

Product Code: GEI

Dated: May 15, 2006

Received: May 17, 2006

Dear Carelle Karimimanesh:

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

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

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

Page 2 – Carelle Karimimanesh

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) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a small "to" written below the main name.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Device Name: VNUS® ClosureFAST™ Catheter

510(k) Number: K061373

Indications for Use:

The VNUS® ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

✓

Prescription Use:  
(21 CFR §801 Subpart D)

or

Over the Counter Use:  
(21 CFR §801 Subpart C)

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

*Barbara Pruchno*  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K061373



**VNUS**<sup>®</sup>  
MEDICAL TECHNOLOGIES, INC.

K061373/A1

31 July 2006

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

Re.: Premarket Notification [510(k)] Submission, amendment to K061373

Dear Dr. Mattamal:

Per our telephone and email communications, enclosed is the replacement page C-2 to substitute in to our K061373 notification for the ClosureFAST™ catheter. The only change on these pages is to conform to that of current 510(k) format.

If you have any questions or require any additional information, please contact me by telephone at 408-360-7261, by fax at 408-365-8480, by email at [ckarimimanesh@vnus.com](mailto:ckarimimanesh@vnus.com).

Sincerely,

Carelle L. Karimimanesh  
Director, Regulatory Affairs

Enclosure: 1 replacement page

RECEIVED  
2006 AUG -1 A 10:54  
FDA/CDRH/ODD/PMO

K9

Device Name: VNUS® ClosureFAST™ Catheter

510(k) Number: K061373

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**Indications for Use:**

The VNUS® ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

✓  
\_\_\_\_\_  
**Prescription Use:**  
(21 CFR §801 Subpart D)

or

\_\_\_\_\_  
**Over the Counter Use:**  
(21 CFR §801 Subpart C)

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

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**CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)**

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

VNUS Medical Technologies, Inc.  
% Carelle Karimimanesh  
Director, Regulatory Affairs  
2200 Zanker Road, Suite F  
San Jose, California 95131

AUG 01 2006

Re: K061373

Trade/Device Name: VNUS<sup>®</sup> ClosureFAST<sup>™</sup>  
Regulatory Number: 21 CFR 878.4400  
Regulatory Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: May 15, 2006  
Received: May 17, 2006

Dear Carelle Karimimanesh:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set 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) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a small "for" written below the name.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Device Name: VNUS® ClosureFAST™ Catheter

510(k) Number: K061373

Indications for Use:

The VNUS® ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

✓

Prescription Use:  
(21 CFR §801 Subpart D)

or

Over the Counter Use:  
(21 CFR §801 Subpart C)

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

*Barbara Prickett*  
\_\_\_\_\_  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K061373

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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

May 17, 2006

VNUS MEDICAL TECHNOLOGIES, INC.  
5799 FONTANOSO WAY  
SAN JOSE, CA 95138  
ATTN: CARELLE L. KARIMIMANESH

510(k) Number: K061373  
Received: 17-MAY-2006  
Product: VNUS CLOSUREFAST  
CATHETER, MODELS  
CF7-7-60 AND  
CF7-7-100

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>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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



K061373

K-8

15 May 2006

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

Re.: Premarket Notification [510(k)] Submission

Dear Reviewer:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR 807, VNUS® Medical Technologies, Inc. (VNUS) is submitting the attached premarket notification in triplicate, and formatted per HHS Publication FDA 95-4158. This application is to declare new model numbers and proprietary names representing several minor changes to the previously cleared VNUS® Closure® Plus catheters (K030557).

<b>Trade Name:</b>	VNUS Closure®FAST™ catheters
<b>Model Numbers:</b>	CF7-7-60 and CF7-7-100
<b>Manufacturer:</b>	VNUS Medical Technologies, Inc. 2200 Zanker Road, Suite F San Jose, CA 95131
<b>Registration Number:</b>	2953189
<b>Classification Name:</b>	Electrosurgical Cutting and Coagulation Devices and Accessories
<b>Regulation Number:</b>	878.4400
<b>Product Code:</b>	GEI
<b>Device Class:</b>	2

The VNUS ClosureFAST catheters have substantially equivalent performance characteristics and intended uses as compared with the named predicate device, which has been cleared by the General and Plastic Surgery division under the specified premarket notification. Direct comparisons of device features, technological characteristics and intended uses are provided in this submission.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of our intention to market these devices.

If you have any questions or require any additional information, please contact me by telephone at 408-360-7261, by fax at 408-365-8480, by email at [ckarimimanesh@vnus.com](mailto:ckarimimanesh@vnus.com).

Please note that our postal address has changed to 5799 Fontanoso Way, San Jose, CA 95138.

Sincerely,

Carelle L. Karimimanesh  
Director, Regulatory Affairs

Handwritten notes: K-8, SU, II

Handwritten initials: 22

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission  
 May 2006

User Fee Payment ID Number  
 (b)(4) Trade Secret

FDA Submission Document Number (if known)

**SECTION A**

**TYPE OF SUBMISSION**

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

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

**SECTION B**

**SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name VNUS Medical Technologies, Inc.		Establishment Registration Number (if known) 2953189	
Division Name (if applicable)		Phone Number (including area code) ( 408 ) 360-7200	
Street Address 2200 Zanker Road, Suite F		FAX Number (including area code) 408-365-8480	
City San Jose	State / Province CA	ZIP/Postal Code 95131	Country USA
Contact Name Carelle Karimimanes			
Contact Title Director, Regulatory Affairs		Contact E-mail Address ckarimimanes@vnus.com	

**SECTION C**

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

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

**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

- Withdrawal
  - Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
  - Software / Hardware
  - Color Additive
  - Material
  - Specifications
  - Other (specify below)

- Location change:
  - Manufacturer
  - Sterilizer
  - Packager

- Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other (specify below)

- Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other (specify below)

- Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (specify):

**SECTION D2**

**REASON FOR APPLICATION - IDE**

- New Device
  - New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
  - Correspondent / Applicant
  - Design / Device
  - Informed Consent
  - Manufacturer
  - Manufacturing Process
  - Protocol - Feasibility
  - Protocol - Other
  - Sponsor

- Report submission:
  - Current Investigator
  - Annual Progress Report
  - Site Waiver Report
  - Final

- Repose to FDA Letter Concerning:
  - Conditional Approval
  - Deemed Approved
  - Deficient Final Report
  - Deficient Progress Report
  - Deficient Investigator Report
  - Disapproval
  - Request Extension of Time to Respond to FDA
  - Request Meeting
  - Request Hearing

- Other Reason (specify):

**SECTION D3**

**REASON FOR SUBMISSION - 510(k)**

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (specify):  
Modified device design, same basic technology and indications for use.

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

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

Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K030557	1	VNUS® Vessel and Tissue Coagulation System	1	VNUS Medical Technologies, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
 Electrosurgical cutting and coagulation device

	Trade or Proprietary or Model Name for This Device		Model Number
1	VNUS ClosureFAST™ catheter	1	CF7-7-60 and CF7-7-100
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

Laboratory Testing     
  Animal Trials     
  Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code GEI	C.F.R. Section (if applicable) 878.4400	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)  
 The ClosureFAST™ catheter is intended for endovascular coagulation of blood vessels in patients with venous reflux.

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

FDA Document Number (if known)

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

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number <b>(b)(4)</b>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name VNUS Medical Technologies, Inc.		Establishment Registration Number 2953189		
Division Name (if applicable) N/A		Phone Number (including area code) ( 408 ) 360-7200		
Street Address 2200 Zanker Road		FAX Number (including area code) ( 408 ) 365-8480		
City San Jose		State / Province CA	ZIP/Postal Code 95131	Country USA
Contact Name Carelle Karimimanesh		Contact Title Director, Regulatory Affairs		Contact E-mail Address ckarimimanesh@vnus.com

**(b)(4) Trade Secret Process**

<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 2953189	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name VNUS Medical Technologies, Inc.		Establishment Registration Number 2953189		
Division Name (if applicable) N/A		Phone Number (including area code) ( 408 ) 360-7200		
Street Address 5799 Fontanoso Way		FAX Number (including area code) ( 408 ) 365-8480		
City Jose		State / Province CA	ZIP/Postal Code 95138	Country USA
Contact Name Carelle Karimimanesh		Contact Title Director, Regulatory Affairs		Contact E-mail Address ckarimimanesh@vnus.com

**SECTION I**

**UTILIZATION OF STANDARDS**

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

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

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

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

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

**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 in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
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 <b>H drive.</b> ]		
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</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
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>

**Premarket Notification [510(k)]  
Checklist for Acceptance Decision**

K \_\_\_\_\_ Date DMC Received: \_\_\_\_\_

**Device Trade Name:** VNUS® ClosureFast™ Catheters

**Reason for 510(k):** The applicant VNUS Medical Technologies, Inc. is expressing its intention to introduce the device into commerce, and this application is submitted as required by regulation [21 CFR 807.81(a)(2)].

**Division/Branch:** General, Restorative, and Neurological Devices

**Administrative Reviewer Signature:**

\_\_\_\_\_ DATE \_\_\_\_\_

**Supervisory Signature:**

\_\_\_\_\_ DATE \_\_\_\_\_

**Did the firm request expedited review** \_\_\_\_\_

**Did we grant expedited review** \_\_\_\_\_

\_\_\_\_\_  
Accepted

\_\_\_\_\_  
Refuse to Accept

Checklist Item	Yes Omission Justified	No Not adequate	Page Locator in 510(k)
<b>I. Critical Elements:</b>			
A. Is the product a device?			N/A
B. Is the device exempt from 510(k) by regulation or policy?			N/A
C. Is device subject to review by CDRH?			N/A
D. (i) Are you aware that this device has been the subject of a previous NSE decision?			N/A
D. (ii) If yes, does the new 510(k) address the NSE issue(s) (e.g., performance data)?			N/A
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.			N/A
E. (ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)			N/A
F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?			
1. Device trade or proprietary name			1-1
2. Device common or usual name or classification name			1-1
3. Establishment registration number (only applies if establishment is registered)			1-1
4. Class into which the device is classified under (21 CFR Parts 862 to 892)			1-1
5. Classification Panel			1-1
6. Action taken to comply with Section 514 of the Act			N/A
7. Proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)			App. D & E
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request			App. C
9. For class III devices only, a class III certification and a class III summary			1-1
10. Photographs of the device			N/A
11. Engineering drawings for the device with dimensions and tolerances			N/A
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device(s)			1-1, 4-1, App. A
13. Statement of similarities and/or differences with Marketed device(s)			4-1

14. Data to show consequences and effects of a modified device(s)			4-4
<b>II. Additional Information that <u>is</u> necessary under 21 CFR 807.87(h):</b>			
A. Submitters name and address			1-1
B. Contact person, telephone number and fax number			1-1
C. Representative/Consultant if applicable			N/A
D. Table of Contents with pagination			i
E. Address of manufacturing facility/facilities and, if Appropriate, sterilization site(s).			1-1
<b>III. Additional information that <u>may be</u> necessary under 21 CFR 807.87(h):</b>			
A. Comparison table of the new device to marketed device(s)			4-1
B. Action taken to comply with voluntary standards			9-1
C. Performance data			
- Marketed Device(s)			
Bench testing			N/A
Animal testing			N/A
Clinical data			N/A
- New Device(s)			
Bench testing			4-1
Animal testing			4-3
Clinical data			N/A
D. Sterilization information for the device and all Accessories			7-1
E. Software information for the device and all Accessories			8-1
F. Hardware information for the device and all Accessories			N/A
G. If this 510(k) is for a kit, has the kit certification Statement been provided?			N/A
H. Is this device subject to issues that have been addressed in specific guidance document(s)?			N/A
If yes, continue review with checklist from any appropriate guidance documents.			N/A
If no, is 510(k) sufficiently complete to allow substantive review?			N/A
I. Other (specify)			N/A

**VNUS MEDICAL TECHNOLOGIES, INC.**

**PREMARKET NOTIFICATION**

**ClosureFAST™ Catheter**  
**15 May 2006**

## Table of Contents

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**I. General Information**

**A. Trade or Proprietary Name**

VNUS® ClosureFAST™ catheter

**B. Common, Usual or Classification Name**

Electrosurgical Device

**C. Establishment Registration Number**

2953189

**D. Address of Manufacturer**

Manufactured By:  
VNUS Medical Technologies, Inc.  
5799 Fontanoso Way  
San Jose, CA 95138

Devices Labeled "STERILE" are Sterilized By:

(b)(4) Trade Secret Process



OR

(b)(4) Trade Secret Process



**E. Contact Person**

Carelle Karimimanesh  
Director, Regulatory Affairs  
Tel: (408) 360-7261  
Fax: (408) 365-8480

**F. Device Classification**

Class II – General and Plastic Surgery Devices

No applicable mandatory performance standards or special controls exist for this device.

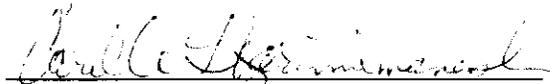
**G. Predicate Device Identification**

VNUS® ClosurePlus™ catheter, cleared in K030557; Predicate Device labeling is contained in Appendix A.

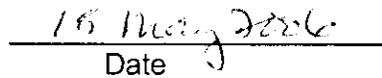
Class III Summary and Certification is not applicable as substantial equivalency is not claimed for, or to, a class III device.

**Truthful and Accuracy Statement**

Pursuant to 21 CFR 807. 87(a), I certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Director, Regulatory Affairs of VNUS Medical Technologies, and in reliance thereupon, the data and information submitted in this Premarket Notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.



Carelle Karimimanesh  
Director, Regulatory Affairs  
VNUS Medical Technologies, Inc.



Date

## **II. Intended Use/Proposed Labeling**

### **A. Statement of Intended Use**

The ClosureFAST™ catheter is intended for endovascular coagulation of blood vessels in patients with venous reflux.

A separate Statement of Intended Use is provided in **Appendix B**.

### **B. Device Labeling**

Product labels and instructions for use are contained in **Appendices D and E**, respectively.

### **C. Advertisements and Promotional Literature**

Advertisement and promotional literature for this device has not been drafted. Future advertisement and promotional literature claims will not exceed stated label claims without appropriate data, documentation and regulatory process.

### III. Device Description

The ClosureFAST™ catheter is provided sterile, and is a single-use, disposable device with an integrated instrument cable and the VNUS RF generator.

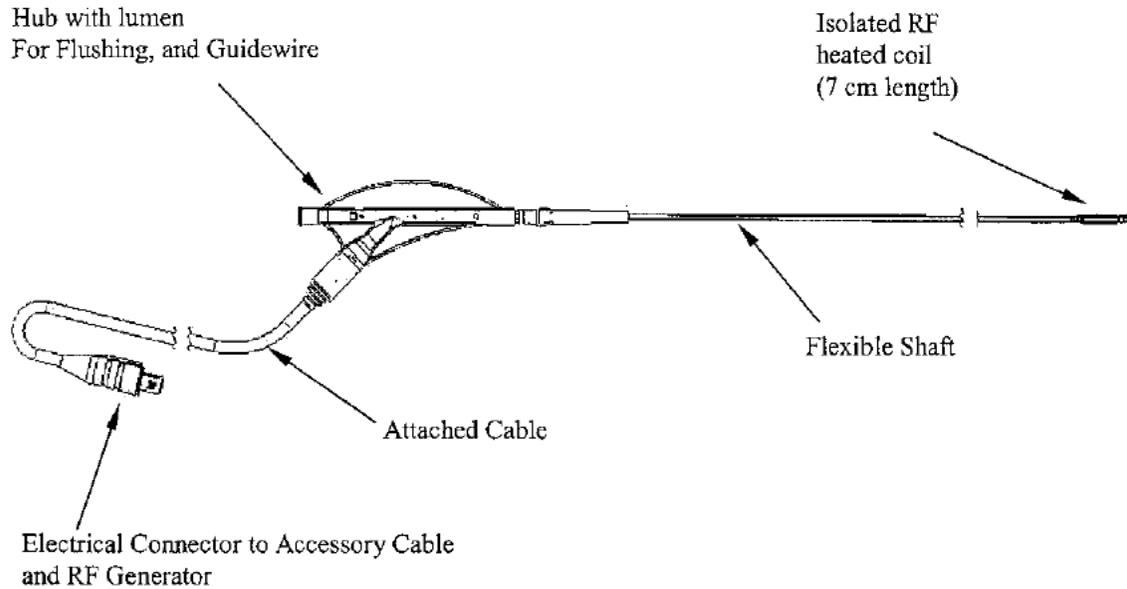
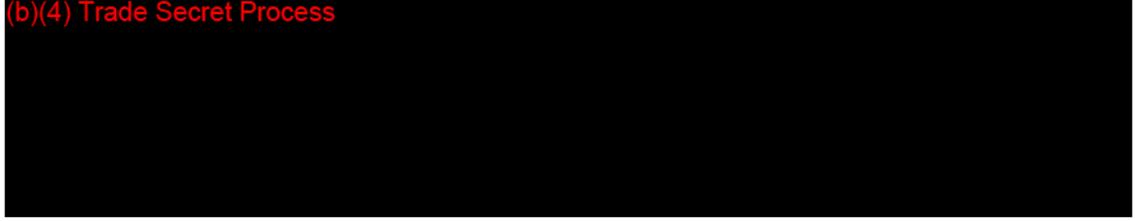


Figure 1: VNUS ClosureFAST catheter with integrated cable

The catheter's function is to coagulate blood vessels by delivering RF energy to a heating element on the catheter that is positioned at a desired treatment site. (b) (4) [REDACTED]. The generator measures temperature, impedance and delivered power. The ClosureFAST catheter is substantially equivalent in function, to the ClosurePlus™ catheter submitted in the referenced Premarket Notification. The subject catheter will have the following differences in design and construction as compared with the ClosurePlus catheter:

(b)(4) Trade Secret Process [REDACTED]

(b)(4) Trade Secret Process



The ClosureFAST catheter is used with the VNUS Radiofrequency Generator, Model RFG2, previously cleared under K040638.

This submission does not include the RF generator or a separate instrument cable. The subject devices are designed to be fully compatible with the previously-cleared VNUS RF generators once the generators have been upgraded to software revision 3.0 or greater. There are no hardware changes required due to the introduction of the additional models of the VNUS ClosureFAST family of devices. The compatibility of the RF generator with the new devices has been or will be verified.

The RF generator is a high frequency (460kHz) electronic, bipolar, microprocessor/ software controlled instrument. It allows the user to set Power, Temperature and Time values, and provides user displays of Power, Temperature and Time (setpoints and measured values). For the ClosureFAST catheter, the impedance will not be displayed. Audible tones and messages provide additional feedback to the physician. The RF generator acts to maintain the set temperature by adjusting the power delivered to the catheter, while not exceeding the maximum set power. By doing so, the RF generator controls the temperature at the thermocouple attached to either the heating element of the ClosureFAST catheter or attached to an electrode of the ClosurePlus catheter. The RF generator works in concert with a catheter ID system to recognize and select appropriate default values for a variety of catheter types. The display screen has the ability to select and display among multiple language choices.

(b)(4) Trade Secret Process



An integrated Instrument Cable is used to connect the ClosureFAST catheter to the RF generator. The Instrument Cable is substantially equivalent in design, manufacture, and materials to the Instrument Cable in the predicate device.

**IV. Comparison with Predicate Device**

**Comparison with the VNUS ClosurePlus catheter and system**

The VNUS ClosureFAST system employs the same principle as the ClosurePlus catheter and system, endovascular temperature-controlled vein wall heating and collagen denaturation, to achieve durable vessel ablation, and uses the same radiofrequency generator (RFG Plus) to power the heating element. The main differences in design and operation between the ClosurePlus and ClosureFAST systems are shown in Table 1.

Table 1: Main design and operational differences between ClosurePlus catheter (K030557) and ClosureFAST catheters

Feature	ClosurePlus catheter and system	ClosureFAST catheter and system
Heating element	(b)(4) Trade Secret Process (b)(4) Trade Secret Process 6F catheter and (b)(4) Trade Secret Process 8F catheter	(b)(4) Trade Secret Process (b)(4) Trade Secret Process (b)(4) Trade Secret Process
Power On/Off switch at catheter	(b)(4)	(b)(4) Trade Secret Process
Catheter Outer Diameter	6 and 8 French	7 French
Catheter lumen and fluid infusion or guidewire	Yes Compatible with 0.025" guidewire Fluid infusion required - using saline or heparinized saline	Yes Compatible with 0.025" guidewire Fluid infusion optional
Pretreatment catheter function test requirement	(b)(4) Trade Secret Process (b)(4)	(b)(4) Trade Secret Process
Catheter movement during vessel ablation	Catheter initially stationary for ~25 seconds then pullback of catheter performed while monitoring rate of withdrawal and vessel temperature	Catheter is typically stationary during energy delivery which occurs over the 7 cm long heating element segment to a segment of the vessel. Catheter and heating element is then moved to next segment of vessel to be ablated.
User Interface for energy delivery	User initiates, User terminates energy delivery	User initiates RF energy delivery which terminates automatically (b)(4) (b)(4) Trade Secret Process
Treatment temperature	(b)(4) Trade Secret Process	(b)(4) Trade Secret Process

The advantages of the ClosureFAST catheter and system over the ClosurePlus catheter and system (b)(4) Trade Secret Process with the ClosureFAST catheter.

Also, with the ClosureFAST catheter (b)(4) Trade Secret Process

[Redacted]

**Bench Testing**

The design of the VNUS ClosureFAST catheter has been verified by performing functional and electrical testing that is designed to subject the catheter to stresses which exceed those which might be encountered during use.

All tests reflect an evaluation against the design input criteria that were set forth in the test protocols (b)(4) Trade Secret Process

[Redacted] Refer to Table 2 for a summary of the type of test and acceptance criteria.

**Table 2 - Design Verification Test Summary**

Test Title	Brief Description of Test	Acceptance Criterion	Comparison with ClosurePlus Criteria	Pass/Fail
Visual Inspection and Dimensional Measurements	(b)(4) Trade Secret Process		[Redacted]	Pass
Printed Outer Shaft Marks Adherence Test	[Redacted]		[Redacted]	Pass
Infusion Lumen Pressure Decay Test	[Redacted]		[Redacted]	Pass
Continuity and Resistance Measurements	[Redacted]		[Redacted]	Pass

**Table 2 - Design Verification Test Summary (continued)**

Test Title	Brief Description of Test	Acceptance Criteria	Comparison with ClosurePlus Criterion	Pass/Fail
Insulation Resistance Test	(b)(4) Trade Secret Process			Pass
Dielectric Withstand Test Mains Frequency				Pass
Dielectric Withstand Test High Frequency				Pass
AC Impedance & Phase Angle Measurements				Pass
Closure Fast RF Power Cycle Test				Pass

Table 2 - Design Verification Test Summary (continued)

Test Title	Brief Description of Test	Acceptance Criteria	Comparison with ClosurePlus Criterion	Pass/Fail
Temperature Response	(b)(4) Trade Secret Process			Pass
Insertion & Withdrawal Through an Introducer Sheath				Pass
Catheter Flexibility				Pass
Catheter Navigation				Pass
Bend Relief Functionality Test				Pass
Functionality After a Kink Test				[1 failure]*
Closure Fast Tip Tensile Test				Pass

(b)(4) Trade Secret Process

**Table 2 - Design Verification Test Summary (continued)**

Test Title	Brief Description of Test	Acceptance Criteria	Comparison with ClosurePlus Criterion	Pass/Fail
Handle Tensile Test	(b)(4) Trade Secret Process			Pass
Closure Fast Hub to Cable Tensile Test				Pass
Handle Drop				Pass
Cable Dielectric				Pass
Electrical Connector Attachment				Pass

***Animal Testing***

A series of experiments was conducted using (b)(4) Trade Secret Process - Testing  
[Redacted]

Objectives

(b)(4) Trade Secret Process - Testing  
[Redacted]

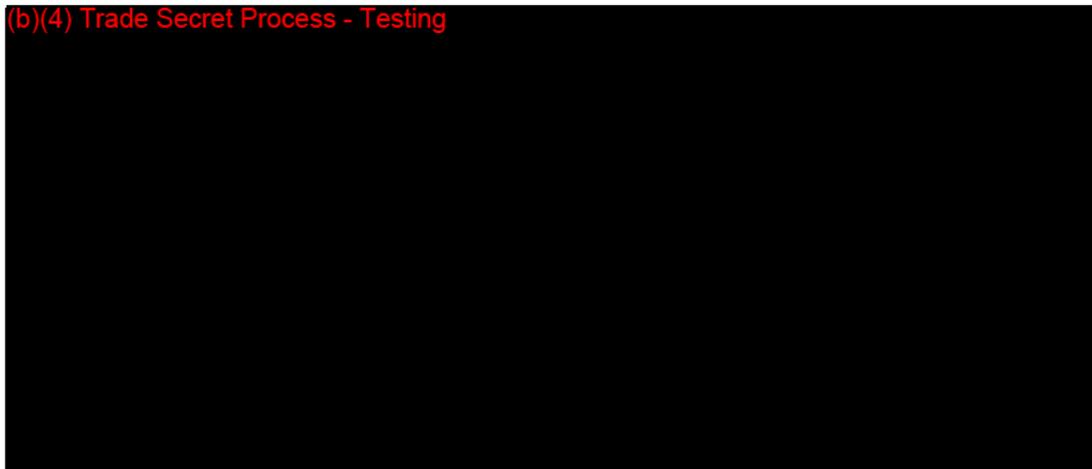
Methods

(b)(4) Trade Secret Process - Testing  
[Redacted]

Results

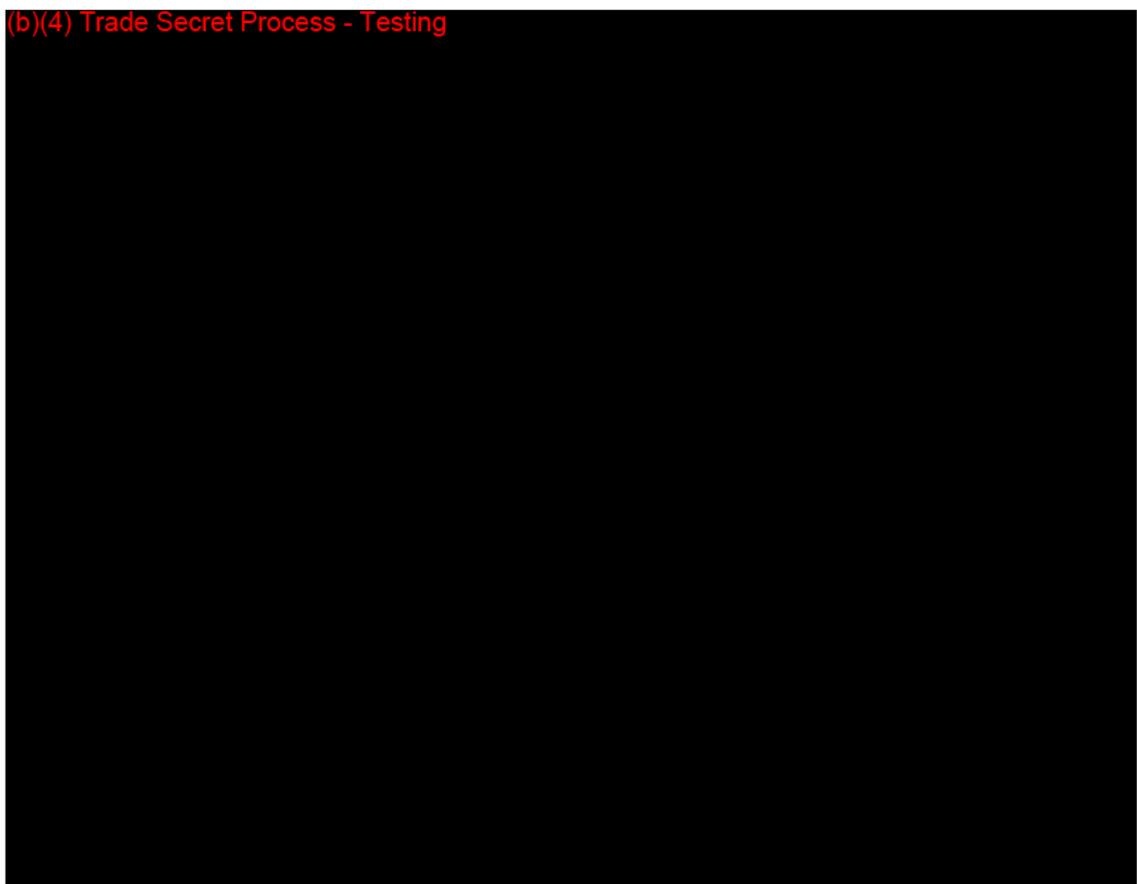
(b)(4) Trade Secret Process - Testing  
[Redacted]

(b)(4) Trade Secret Process - Testing



Discussion

(b)(4) Trade Secret Process - Testing



Animal Study Conclusions

(b)(4) Trade Secret Process - Testing



**Clinical Background**

***Chronic Venous Insufficiency***

Chronic venous insufficiency (CVI) is a common, debilitating disorder that progresses with age if left untreated. It is characterized by symptoms and signs produced by venous hypertension as a result of structural or functional abnormalities of veins. The clinical presentations of CVI range from varicose veins through chronic lower extremity pain and edema to venous skin changes and ulceration. The disorder is associated with a significant reduction in quality of life and the lost of productivity in patients.

The treatment options include conservative therapy such as compression stockings or leg elevation to temporarily relieve symptoms, traditional saphenous vein stripping and ligation surgery, and endovenous thermal ablation such as endovenous radiofrequency or laser ablation. Recurrent reflux after traditional vein stripping surgery is 20% at 2-3 yr, 25% at 5 yr and up to 60% over 30 years.<sup>2</sup>

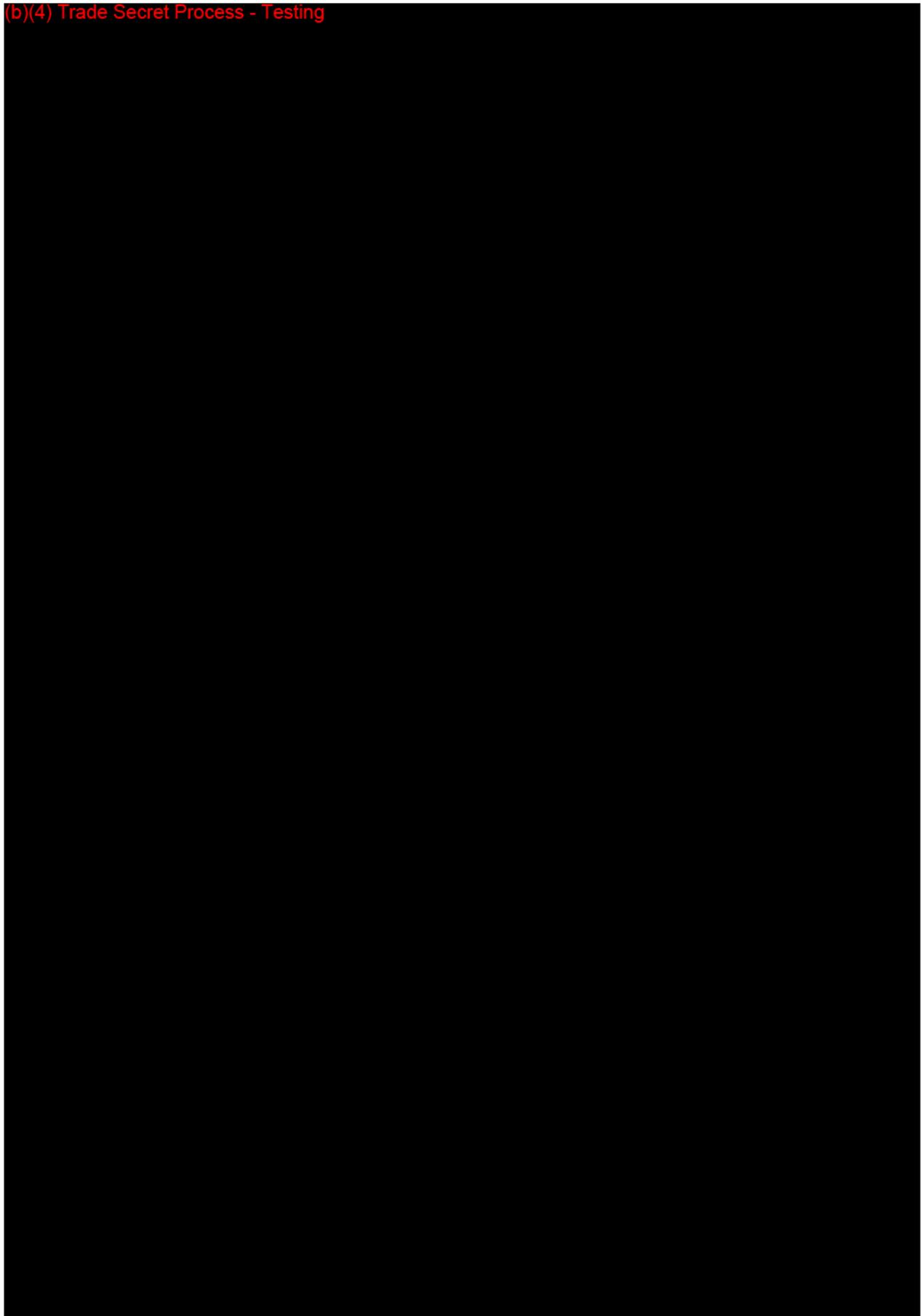
***Endovenous Radiofrequency Ablation***

FDA first cleared the VNUS Closure system in 1999. This was the first use of endovenous radiofrequency ablation (RFA) for endovenous coagulation of blood vessels in patients with superficial venous reflux. It has been used to treat saphenous reflux as an alternative to vein stripping surgery. (b)(4) Trade Secret Process - Testing

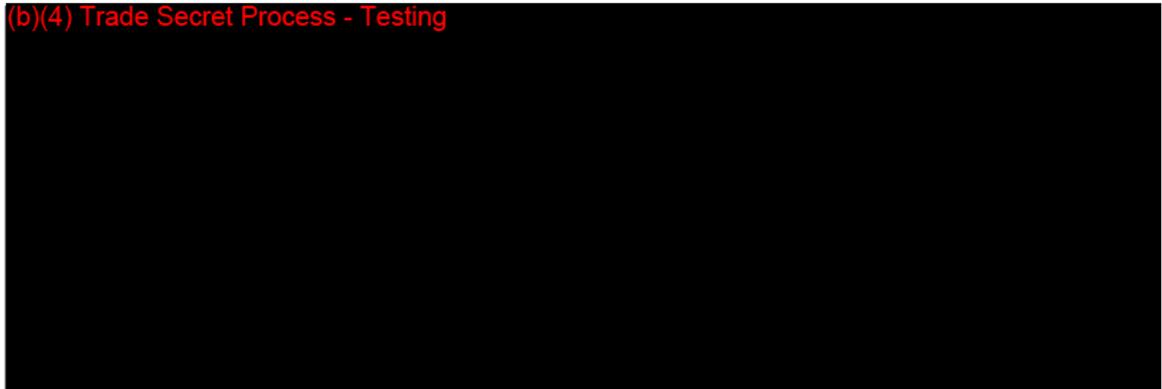
[Redacted]

(b)(4) Trade Secret Process - Testing	[Redacted]						
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

(b)(4) Trade Secret Process - Testing

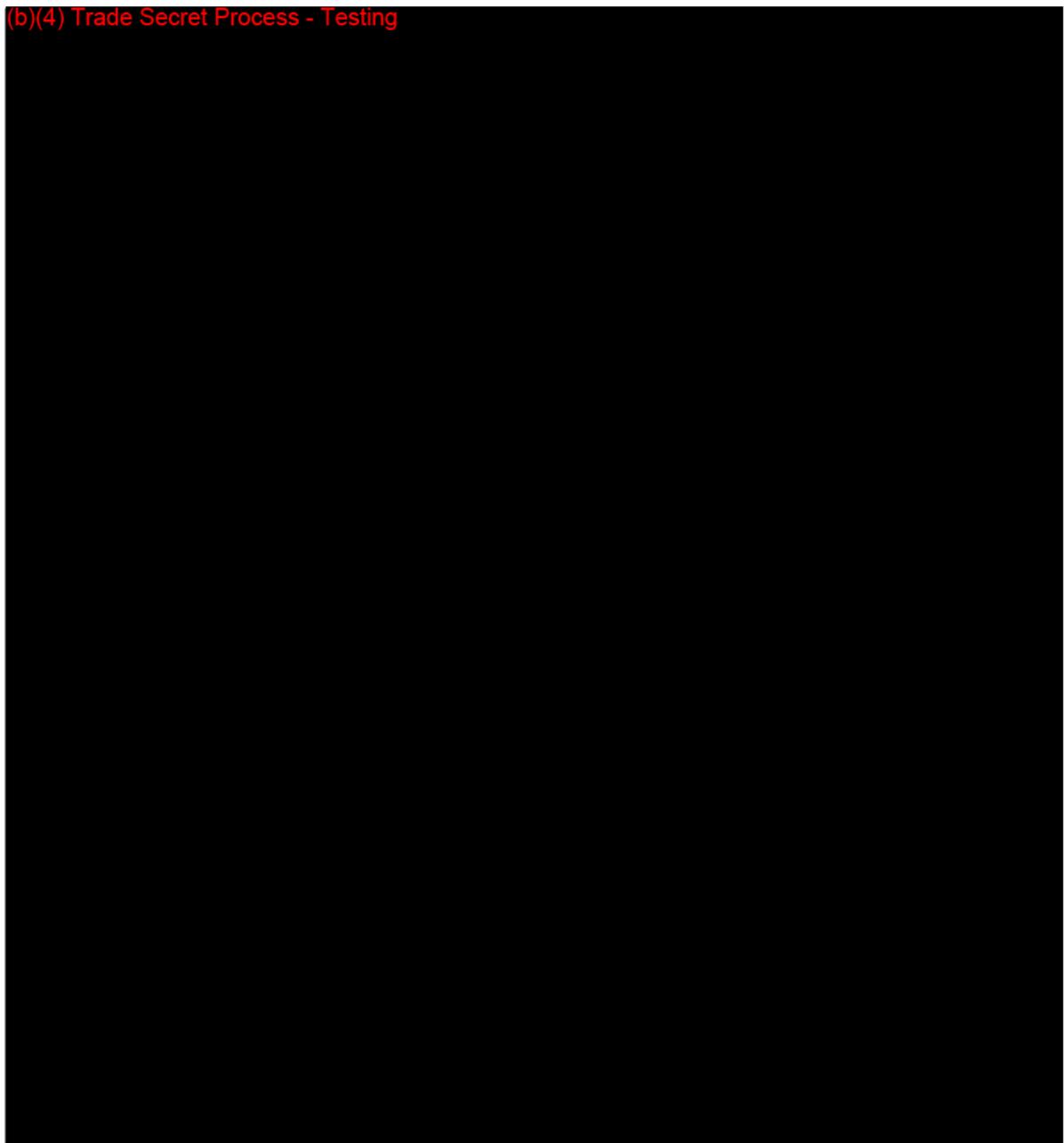


(b)(4) Trade Secret Process - Testing

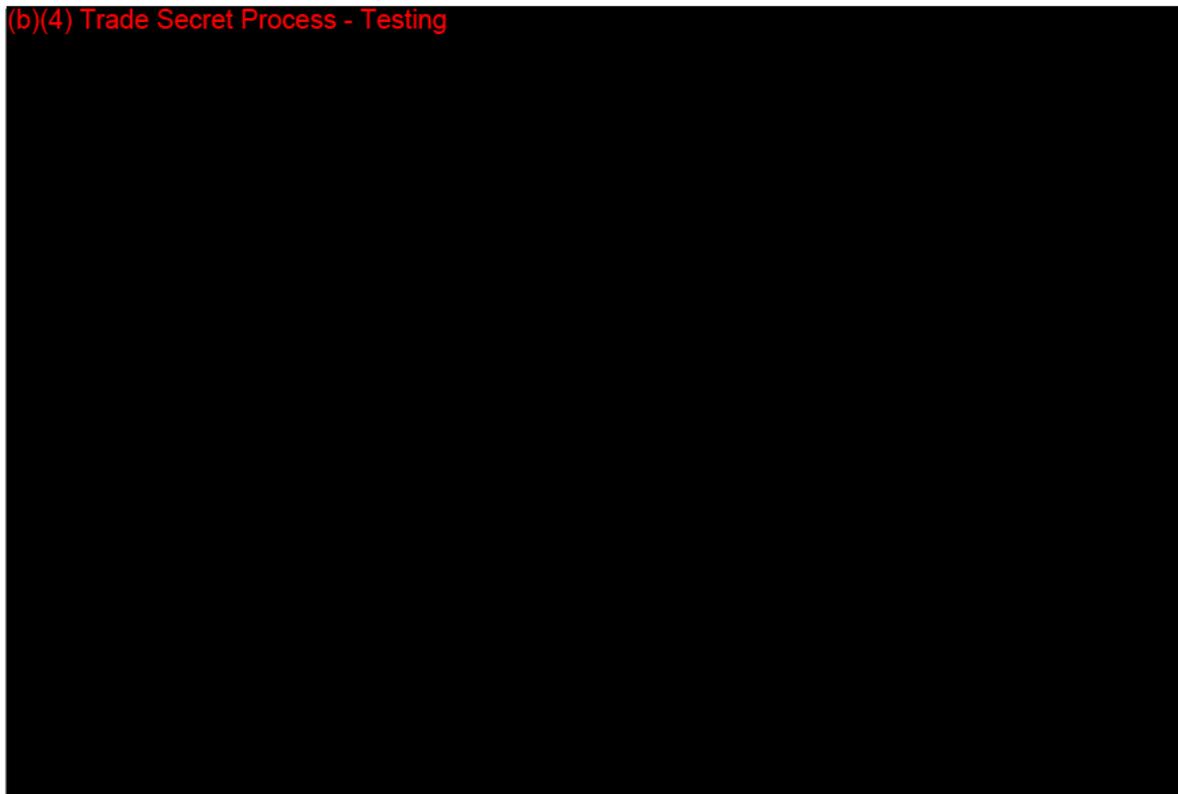
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References:

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing



## V. Quality Systems

VNUS Medical Technologies, Inc. has implemented Quality Systems which were developed in conformance with the U.S. FDA Quality System/cGMP Regulations, ISO 13485:1996 and 2003, and the EC Medical Devices Directives (93/42/EEC). These systems have been audited by FDA, Food and Drug Branch of California, as well as by an ISO Registrar and EU Notified Body, (b)(4) Trade Secret Process.

The design and development of the ClosureFAST catheter have been performed under the VNUS Design Control program. This includes risk management, design verification testing, routine design review meetings, fabrication of samples and products to approved documentation, and documented qualification protocols and reports.

All tests performed through design qualification have confirmed component and finished product durability and repeatability, and provide required assurances of substantially equivalent safe and efficacious performance of the VNUS ClosureFAST catheter devices to the noted predicate device.

## VI. Biocompatibility Testing

The materials used to fabricate the portions of the ClosureFAST catheter which may have patient contact have undergone and successfully passed biocompatibility testing per ISO 10993 for externally communicating devices which contact circulating blood for a limited duration (< 24 hours).

(b)(4) Trade Secret Process - Testing



The summary report and actual test reports for biocompatibility testing are found in Appendix F.

## VII. Sterilization

### *Sterility Assurance*

The VNUS ClosureFAST catheter with integrated instrument cable is terminally sterilized via electron beam (e-beam) irradiation. This process has been validated to produce a sterility assurance level (SAL) of  $10^{-6}$  in accordance with AAMI/ISO 11137 and AAMI TIR 27 to substantiate (b)(4) Trade Secret ) dose.

### *Validation Method*

The e-beam irradiation process has been validated (b)(4) Trade Secret Process - Testing  
h included (b)(4) Trade Secret Process - Testing

### *Shelf Life*

The ClosureFAST catheter is packaged in a standard Tyvek pouch which has a long history of use in medical device packaging and with VNUS catheters in particular. Initially, the product will be labeled with a six month expiration date.

Two year shelf-life will be validated using accelerated aging methods. This testing includes a rigorous battery of mechanical testing and package integrity testing including dye penetration, burst/creep, and peel strength.

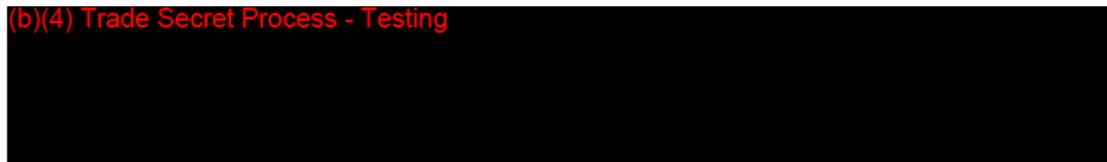
### *Pyrogen Testing*

A representative from the VNUS ClosureFAST catheter family has been tested for pyrogens via (b)(4) Trade Secret Process - Testing to demonstrate that the blood contact portions of the catheter are indeed non-pyrogenic per FDA guidelines (b)(4) Trade Secret Process - Testing

## VIII. Software Validation

Software controls the overall operation of the VNUS RF generator. Software allows the operator to select the maximum allowed Power, Temperature set point, and duration of RF output. Software also provides On/Off control of the output or selection of a test mode. When the RF generator is in the Standby mode, the software displays the operator settings. When the RF generator is in the Treatment Ready mode, it is ready and waiting for a START/STOP button to be depressed, beginning delivery of RF energy. When the RF generator is delivering RF energy, software measures and displays the values of output power, temperature, and elapsed time and displays these measurements on the front panel.

(b)(4) Trade Secret Process - Testing

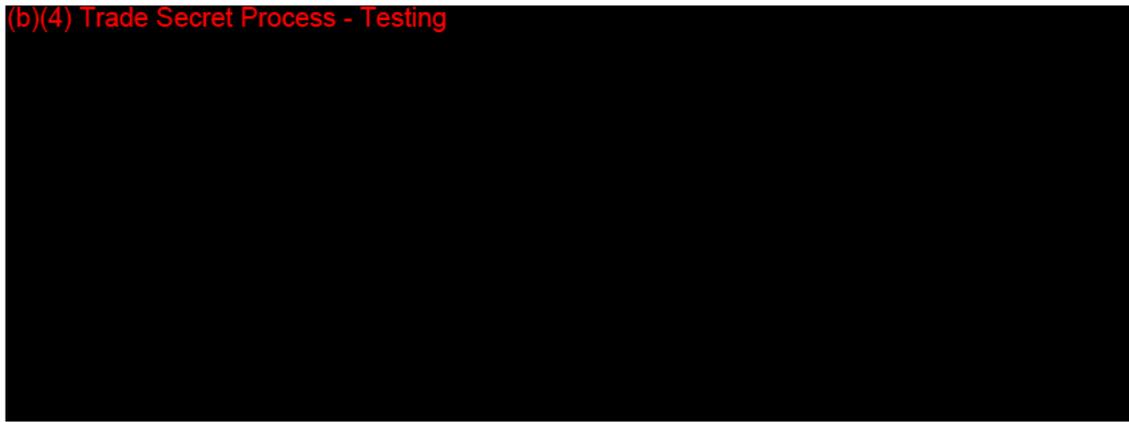


The software used in the VNUS RF generator was developed and validated per programs which are based upon the U.S. FDA *Reviewer's Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*.

The VNUS RF generator is a moderate level of concern medical device. Product Requirements Documents (including Product Specification, Software Requirements Specification, Hazards Analysis, and Software Design Specification elements) were developed for the device. The software is verified and validated to the Product Requirements Documents in accordance with approved protocols and test plans. These documents provide the test plans and test completion criteria, all expected results and outcomes, and the verification and validation criteria that must be demonstrated by the software. In addition, the documents include the control of hazards and the performance of safety functions. The software verification and validation is documented in approved test reports maintained in the Design History Files.

### ***General Description of the Software Development Process***

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing

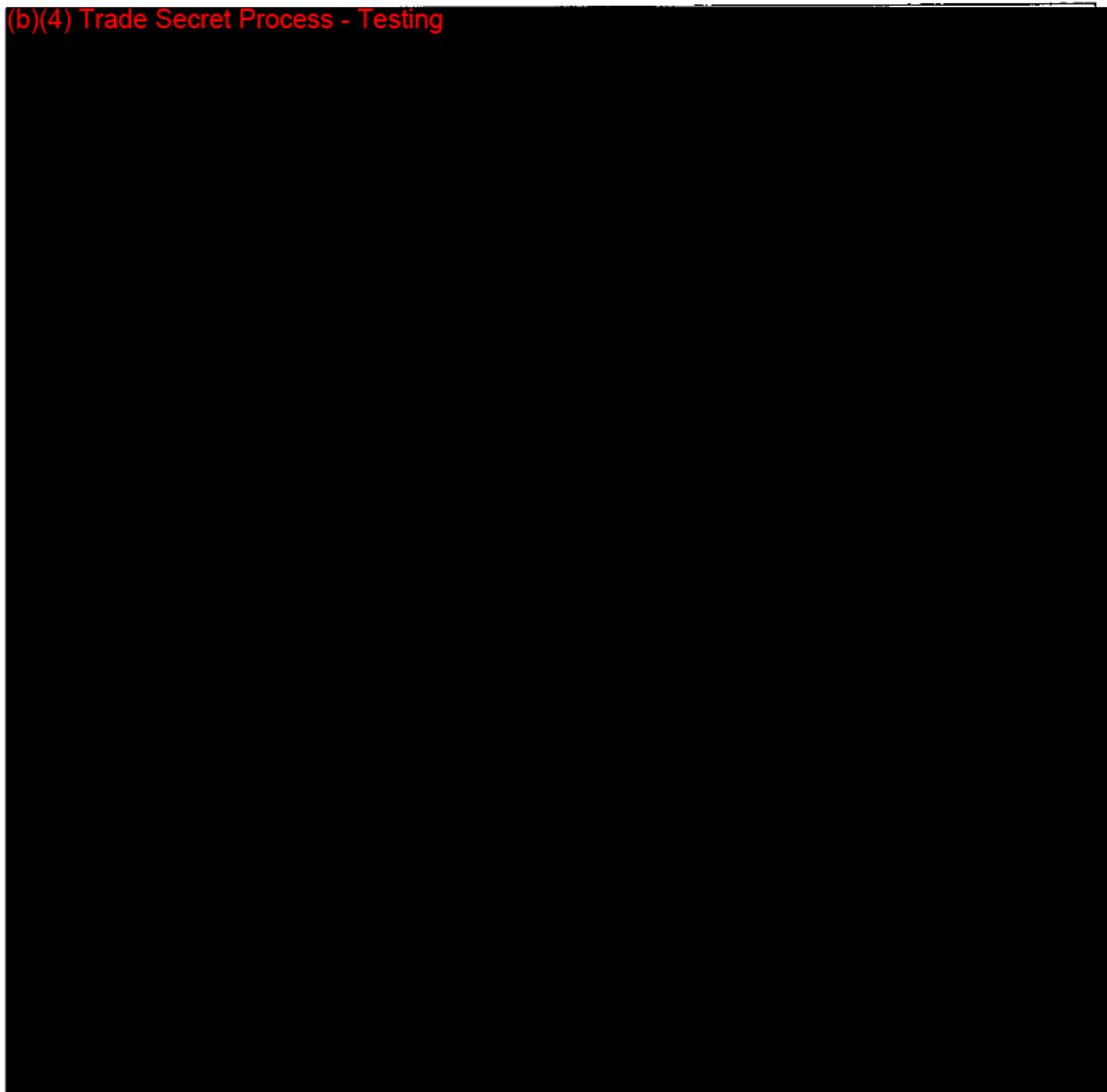


Future revisions to the released requirements or design specifications or to the code are controlled through a process that begins with a change request, followed by implementation, code review, and validation and verification for the portion of the code that changed.

## IX. References of Standards and Guidances Used

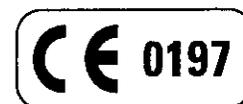
Applicable sections of the following Reference Standards and Guidance documents used for product testing:

(b)(4) Trade Secret Process - Testing



## Appendix: A

# PREDICATE DEVICE LABELING VNUS® Closure® Plus Catheter



**VNUS® Closure® PLUS Catheter – Instructions For Use**

**NOTE:** Carefully read all instructions, including the VNUS RF generator Operator’s Manual, thoroughly prior to using the Closure System. Observe all warnings, precautions and cautions noted throughout these instructions. Failure to do so may result in patient complications.

⊗ Single Use Only

STERILE R Sterilized by irradiation.

⚠ Attention: Contents are sterile unless package is open or damaged. For use with the VNUS RF generator only.

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

**Supplies and Equipment**

- VNUS RF generator
- Tilt table
- IV pressure bag
- 0.5 to 1.0 liter of 10 units/cc heparinized saline
- 18 gauge thin-walled or 19 gauge ultra thin-walled needle (for percutaneous access)
- Introducer sheath (see table below for correct size)
- Esmark bandage (elastic compression wrap, optional)
- Ultrasound scanner
- Sterile ultrasound gel
- Sterile ultrasound transducer cover
- Y-connector with hemostasis valve (optional)
- Backcheck valve (optional)
- 20 or 22 gauge X 3.5” spinal needle for tumescent fluid infiltration (optional)
- .025” Guidewire (optional)

Catheter Model	CL6	CL8
Introducer Sheath (Minimum French size)	6F (2.0mm)	8F (2.67mm)
Electrodes Expand to (mm)	8mm	12mm

**Device Description**

The VNUS Closure System consists of two main components: The Closure PLUS Catheter and the RF generator. The Closure PLUS Catheter is provided sterile, and is a single-use, disposable device. The Closure PLUS Catheter’s function is to provide RF energy to the desired treatment site and relay temperature and other feedback to the RF generator. The RF generator remains out of the sterile field during use, and is provided non-sterile. The catheter is connected to the RF generator via the included attached sterile cable.

Indications

The Closure System is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Contraindications

- Patients with thrombus in the vein segment to be treated.

**PRECAUTION:** For the patients with a pacemaker, internal defibrillator or other active implanted device, consult the cardiologist and the manufacturer of the active implanted device. Continuous patient monitoring during the procedure is recommended. Evaluate the patient and the implanted active device post procedure. Keep all power cords and the attached sterile cable away from the location of the pacemaker or leads, defibrillator or the implanted active device.

**CAUTION:** In patients with an aneurysm in the vein segment to be treated, the vein wall may be thinner in the area of the aneurysm. To effectively occlude a vein with an aneurysmal segment, additional tumescent infiltration may be needed over the aneurysmal segment, and the treatment of the vein should include segments proximal and distal to the aneurysmal segment.

**CAUTION:** No data exists regarding the use of this catheter in patients with documented peripheral arterial disease. The same care should be taken in the treatment of patients with significant peripheral arterial disease as would be taken with a traditional vein ligation and stripping procedure.

#### Potential Complications

The potential complications include, but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia, skin burns.

**WARNING:** TREATMENT OF A VEIN LOCATED CLOSE TO THE SKIN SURFACE MAY RESULT IN A SKIN BURN.

**WARNING:** PARESTHESIA MAY OCCUR FROM THERMAL DAMAGE TO ADJACENT SENSORY NERVES. RISK OF PARESTHESIA IS HIGHER WITH TREATMENT AT OR BELOW THE CALF.

#### Catheter Inspection & Preparation

- 1) Inspect outer box for signs of visible damage.
- 2) Remove sterile pouch from box and inspect for damage (i.e., tears, punctures etc.). If pouch is damaged, do not use catheter.
- 3) Peel pouch open from the end closest to handle (chevron).
- 4) Move the slider control in the catheter handle forward so that the outer shaft covers and protects the electrodes.
- 5) Using sterile technique remove catheter from pouch chipboard tray.
- 6) Move the slider control in the catheter handle back to allow the electrodes to self-expand. Assure that the flexible electrodes are symmetrically arranged and are not bent or otherwise damaged. If the catheter is damaged, DO NOT USE THE CATHETER. After inspection, move the slider control in the catheter handle forward so that the outer shaft covers and protects the electrodes.
- 7) Pass the end of the attached cable out of the sterile field, for later connection to the RF generator.
- 8) Flush catheter lumen and disposable accessories with sterile, physiologic saline (0.9% sodium chloride) or heparinized saline. Wipe outer surface of catheter with saline or heparinized saline.
- 9) If the optional guidewire will be used, refer to the guidewire manufacturer's instructions for use. Attach the Y-connector with backcheck valve to the luer adapter on the catheter handle, and re-flush as necessary to remove all air. Load the guidewire into the catheter lumen, positioning the soft tip just inside the catheter tip to prevent wire damage during insertion into the vein. Tighten the hemostasis valve on the Y-connector to prevent back-bleeding and wire migration. Catheter preparation is now complete.

- 10) If the optional guidewire will not be used, attach the one-way flush valve to the luer adapter on the catheter handle. Catheter preparation is complete.

**Note: Refer to the Operator's Manual for the appropriate model of the VNUS RF generator.**

Generator Set-up & Operation

- 1) Plug in RF generator.
- 2) Turn power "ON" using toggle switch on rear panel.
- 3) Connect the catheter cable to the RF generator.
- 4) Default treatment settings for the Closure *PLUS* Catheter are: 6 Watts, 85°C, and 999 seconds. Reference the RF generator Operator's Manual for instructions on changing the settings.

Note: The default settings will not be displayed until a catheter is connected to the RF generator. Default settings may be adjusted according to physician preference.

### **System Check by Saline Test (Optional)**

- 1) Deploy the electrode array and immerse the electrodes in a bowl of sterile, physiologic saline or heparinized saline.
- 2) Refer to the Operator's Manual for the RF generator. An impedance value of approximately 100 – 150  $\Omega$  (6F catheter) or approximately 40 – 70  $\Omega$  (8F catheter) and a temperature of approximately 20°C (room temperature) should be observed, when in saline.

Note: These stated values may further vary due to the actual saline temperature.

- 3) Move the slider control in the catheter handle forward so that the outer shaft covers and protects the electrodes.

## PATIENT PREPARATION AND TREATMENT

- 1) If local anesthetic is employed, administer local anesthetic at the vein access site. Mild sedation may also be given.

Note: Venospasm may hinder the ability to access the target vein and to perform the Closure procedure. Therefore, factors which may induce venospasm such as certain drugs, a cold environment, or patient anxiety, should be avoided.

- 2) Position the patient for vein access. Lowering the patient's legs below the level of the heart will increase vein diameter, which may facilitate vein access. For treatment, positioning the patient's legs horizontal to or above the level of the heart will assist in reducing vein diameter and reduce venous filling prior to treatment.
- 3) Access the vein to be treated via a percutaneous stick using an 18 gauge thin-walled or 19 gauge ultra thin-walled needle or via a small cut-down.
- 4) Prepare and place introducer sheath per manufacturer's instructions for use.
- 5) Start the heparinized saline infusion (10 units/cc, 2 cc/min) through the catheter's central flush lumen using a pressurized bag.

**CAUTION: IF THE INFUSION RATE IS NOT REGULATED, THE RATE OF INFUSION WILL BE GREATER THAN THE RECOMMENDED 2CC/MIN. FAILURE TO REGULATE THE INFUSION RATE TO 2CC/MIN MAY YIELD UNPREDICTABLE RESULTS.**

- 6) Insert the Closure *PLUS* catheter into vein and advance the catheter tip to the point where treatment will begin. Position the catheter in the vein using palpation or ultrasound.

**CAUTION: THE OUTER SHAFT MUST ALWAYS BE POSITIONED TO COVER THE ELECTRODES WHEN INTRODUCING THE CATHETER INTO THE VEIN AND WHEN MOVING THE CATHETER INTO POSITION FOR TREATMENT. FAILURE TO ASSURE THIS MAY RESULT IN DAMAGE TO THE CATHETER AND/OR POTENTIAL INJURY TO THE PATIENT.**

If an optional guidewire is necessary, refer to Step 9 in Catheter Inspection & Preparation for instructions on loading the guidewire into the catheter. Once the guidewire is loaded properly, insert the catheter tip into the vein and loosen the hemostasis valve on the Y-connector. Advance the guidewire to the desired location and maintain wire position while advancing the catheter tip. Remove the guidewire completely from the catheter once the catheter has been positioned at the treatment site to allow infusion of heparinized saline.

**CAUTION: DO NOT ADVANCE THE CATHETER AND/OR GUIDEWIRE AGAINST RESISTANCE, OR VEIN PERFORATION MAY OCCUR.**

- 7) If local anesthesia is employed, administer local anesthetic along the vein segment to be treated.

Note: Tumescent infiltration of saline or dilute local anesthetic should be administered when the vein is located close to the skin surface.

- 8) Create a near-bloodless field for the catheter electrodes by occluding flow in the superficial venous network and ensuring the vessel to be treated is compressed prior to treatment. This is accomplished with one or more of the following steps.

- Tumescent infiltration of saline or dilute local anesthetic into tissue in proximity with the vessel to be treated. Use sufficient volume to exsanguinate.
- Tightly wrap an Esmark bandage from the base of the toes to the uppermost portion of the thigh. This wrap may not be necessary if a sufficient volume of tumescent infiltration is used to exsanguinate the vein.
- Position the legs of the patient above the heart to facilitate exsanguination and vein collapse.
- Apply external compression over the treatment area if desired.

- 9) Move the slider control in the catheter handle back to retract the outer shaft. Confirm and re-adjust if necessary catheter tip position using ultrasound or palpation.

**CAUTION: NEVER ADVANCE THE CATHETER WITH THE ELECTRODES OPEN. DAMAGE TO THE VEIN AND/OR CATHETER MAY RESULT.**

- 10) Slide the two adjustable markers up to the access site to mark the starting location of the catheter within the vein. This will assist in monitoring the length of vein treated during the procedure.

- 11) Once the tip has been positioned, verify contact between the electrodes and the vein wall as indicated by the measured impedance by pressing the test button. Refer to the Operator's manual for the RF generator. Test values of 33 to 39°C and  $\geq 200 \Omega$  (6F) or  $\geq 150 \Omega$  (8F) are acceptable.

Note: The test temperature may be as low as 28°C following previous infiltration of room temperature fluid.

- 12) Start the RF energy delivery by pressing the "RF ON/OFF" button. If the RF ON/OFF button does not light up, observe any displayed error message and refer to the Operator's Manual for the RF generator.

- 13) Wait until the set temperature is reached (approximately 10 seconds).

Note: If the set temperature is not reached within 10 to 15 seconds after RF energy delivery, there may be flow within the vein that is cooling the treatment segment. Terminate RF energy delivery, verify effectiveness of flow occlusion and proper tip position, correct as necessary, and re-initiate treatment of the segment.

- 14) Maintain set temperature for at least 15 seconds, keeping the catheter stationary. After 15 seconds, the pullback timer will begin counting.

- 15) Slowly withdraw the catheter while continuously monitoring the temperature on the RF generator display. The rate of catheter withdrawal must be slow enough to maintain the temperature within -3°C of the set temperature. Catheter withdrawal rate is typically 1cm per minute for the first 5 minutes then 2 to 3cm per minute for the remainder of the treatment. The 1 cm white graduation marks on the catheter shaft should be used to maintain the desired withdrawal rate. **Failure to maintain temperature and catheter withdrawal rate in this target operating range may result in an incomplete treatment.** (Brief, transient readings of up to  $\pm 5^{\circ}\text{C}$  may occur during catheter movement and will not affect the treatment outcome.)

Note: Continuous readings below the default temperature may result in incomplete treatment. If this occurs, stop catheter withdrawal until the set temperature is re-achieved. Then allow the temperature to stabilize at the set temperature for 15 seconds. After this time period, continue catheter movement at a rate slow enough to keep the temperature within -3°C of the default temperature.

Note: If the system shuts down and shows a high impedance condition, this may indicate that the catheter was withdrawn too quickly in the vein, that external compression is inadequate (see step 8), or that the electrodes are no longer within the collapsed vein segment. Slide the first adjustable marker up to the access site, close the electrodes and remove the catheter from the vein. Check for and remove any coagulum from electrodes using a heparin/saline wetted sponge. Close the outer shaft, loosen the external compression to facilitate catheter reinsertion, and re-insert the catheter up to the position of an adjustable marker. Once the catheter is repositioned, reapply external compression and continue the procedure starting at step 9.

Note: If LCD screen reads, "... withdraw catheter 1 to 2mm", this may indicate a condition in which the target temperature can not be maintained. When this condition occurs the generator's audible tone will occur at an increased rate. In this case, withdraw the catheter slowly 1 to 2mm and hold position until the set temperature is regained. Once set temperature is reached, hold for at least 15 seconds, then resume withdrawal at the normal rate. Once normal conditions have been reached, the audible tone will return to a normal rate.

- 16) Once the electrode tip has reached the end of the collapsed vein segment, press the "RF ON/OFF" button to terminate RF energy delivery.
- 17) Evaluate the treated vein segment to determine the existence of residual flow, vein wall thickening and luminal reduction. Retreat if necessary to further shrink vein or occlude flow.
- 18) If additional vein segments are to be treated, repeat steps 6 through 17 at the new site(s).
- 19) After treatment, withdraw the catheter, remove the external compression, and obtain hemostasis at the access site.

## FOLLOW-UP CARE

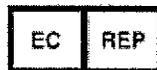
- 1) Follow-up examination within 72 hours should include an assessment to ensure that there is no thrombus extension into deep veins.

## PRECAUTIONS

- Store in a dry, cool place.
- Do not use catheter if package is opened or damaged, as sterility is not guaranteed.
- To avoid kinking, do not bend catheter. Kinking of the shaft may result in inability to deploy electrodes.
- To prevent damage to the guidewire, ensure that the guidewire does not protrude from the catheter tip when inserting catheter into vein.
- To prevent damage to the electrodes, ensure that the outer shaft is full forward and use care when inserting catheter into the vein.
- Do not move catheter inside the vein (other than during withdrawal while treating) with the electrodes expanded.
- Do not advance catheter and/or guidewire against resistance.
- Do not rotate or torque catheter with electrodes expanded.
- Do not deliver RF energy with the outer shaft over the electrodes.
- Use Closure *PLUS* catheters only with VNUS RF generator.
- **Treatment of a vein located close to the skin surface may result in a skin burn.**
- **Paresthesia may occur from thermal damage to adjacent sensory nerves. Risk of paresthesia is higher with treatment at or below the calf.**

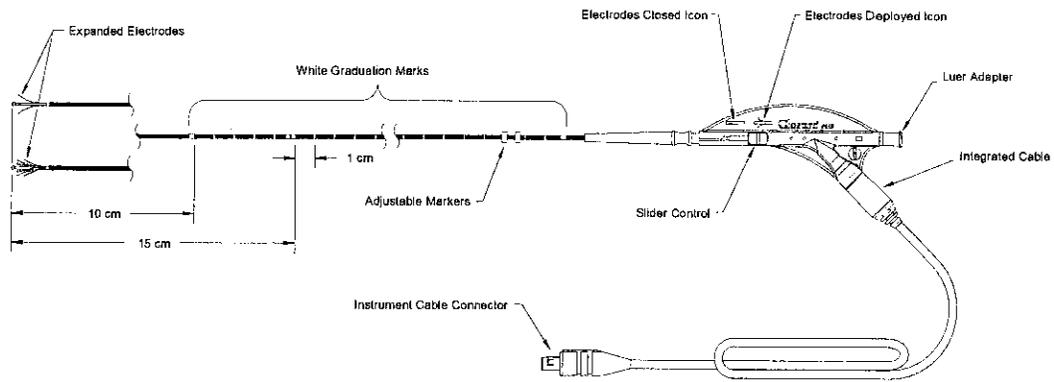


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Manufactured under one or more of the following U.S. Patent Nos. 6,071,277 & 6,152,899 & 6,165,172 & 6,179,832 B1 & 6,200,312 B1 & 6,237,606 B1 & 6,258,084 B1 & 6,401,719 B1 and Patents Pending.



## **Appendix: B**

### **Statement of Use**

Device Name: VNUS® ClosureFAST™  
Catheter

510(k) Number (if known):

Indications for Use:

The VNUS® ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with venous reflux.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:  
(Per 21 CFR 801.109)

or

Prescription Use:

*See R Revised one*

## **Appendix: C**

# **Summary of Safety and Effectiveness**



**510 (k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: 15 May 2006

510(k) number: \_\_\_\_\_

**Applicant Information:**

VNUS Medical Technologies, Inc.  
5799 Fontanoso Way  
San Jose, CA 95138

Contact Person: Carelle Karimimanesh  
Phone Number: (408) 360-7261  
Fax Number: (408) 365-8480

**Device Information:**

Classification: Class II  
Trade Name: VNUS<sup>®</sup> ClosureFAST™ Catheter  
Classification Name: Electrosurgical Device (21 CFR §878.4400)

**Equivalent Device:**

The subject device is substantially equivalent in intended use and/or method of operation to the VNUS<sup>®</sup> ClosurePlus™ Catheter (K030557).

The technological characteristics and principals of operation of the VNUS ClosureFAST catheter are substantially equivalent to the noted predicate device. Both devices rely on the delivery of RF energy to an intravascular catheter that heats a blood vessel to a specific temperature to achieve the intended use.

**Intended Use:**

The VNUS<sup>®</sup> ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with venous reflux.

**Test Results:**

*Performance*

Results of *in vitro* testing demonstrate that the VNUS ClosureFAST catheter is substantially equivalent to the predicate device effective for its intended function.

*Biocompatibility*

The materials used in the VNUS ClosureFAST Catheters have been shown to be biocompatible.

**Summary:**

Based on the intended use, product performance, and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

## **Appendix: D**

# **DRAFT PRODUCT LABELS VNUS® ClosureFAST catheter**

**Open Other End** 00000

00000

LOT 000000

cm 00

(2.33mm) 7F

REF CF7-7-00

LOT 000000

200X-00

**ClosureFAST™**

**Caution: Investigational device. Limited by Federal (or United States) law to investigational use only.**

ClosureFAST™

REF CF7-7-00

**7F**

(2.33mm)

**00** cm

Usable Length/ Brukbara Lengd/ Longueur Utilisable/ Verwendbare Länge/ Lunghezza Utilizzabile/ Longitud de Uso/ Användbar Längd

REF CF7-7-00

LOT 000000

200X-00

Attention, see instructions for use. For use with VNUS RFG Plus Radiofrequency Generator only. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

STERILE R GW .025"

One or more of the following patents may apply: 6,237,606 & 6,258,084 & 6,630,273 & 6,752,803 & 6,789,433 and other U.S. and International applications pending.

Manufactured by:

**VNUS**<sup>®</sup>

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SA70-121-XX Rev 2

ClosureFAST™ 7F 00 cm

REF CF7-7-00

LOT 000000

200X-00

ClosureFAST™ 7F 00 cm

REF CF7-7-00

LOT 000000

200X-00

## **Appendix: E**

### **Draft Instructions for Use**

## VNUS® ClosureFAST™ Catheter – Instructions For Use

**NOTE:** Thoroughly read all instructions, including the VNUS® RFGPlus™ RF generator Operator's Manual, prior to using the Closure® system. Observe all warnings, precautions and cautions noted throughout these instructions. Failure to do so may result in patient complications.

⊗ Single Use Only

STERILE | R Sterilized by irradiation

⚠ Attention: Contents are sterile unless package is open or damaged. For use with the VNUS RFGPlus RF generator only.

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

Caution: **DO NOT** steam sterilize or autoclave (device is single use only).

### *Supplies and Equipment:*

- VNUS RFGPlus RF generator (software version 3.0 or later)
- Tilt table
- Duplex ultrasound scanner
- Sterile ultrasound gel
- Sterile ultrasound transducer cover
- 18G thin-walled or 19G ultra thin-walled needle (for percutaneous access)
- 7F introducer sheath (11 cm length recommended)
- 20 or 22G, 3.5" long spinal needle for tumescent fluid infiltration
- Stopcock or one-way flush valve (optional)
- 0.025" guidewire (optional)
- IV pressure bag (optional)
- Esmark bandage (elastic compression wrap) (optional)

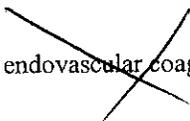
Catheter Model	CF7-7-60	CF7-7-100
Introducer Sheath (Minimum ID size)	7F (2.33mm)	7F (2.33mm)
Insertable Length (cm)	60cm	100cm
Heating Element Diameter	2.25mm	2.25mm
Heating Element Length	7cm	7cm

**Device Description**

The VNUS Closure system consists of two main components: The ClosureFAST™ catheter and the RFGPlus RF generator. The ClosureFAST catheter is provided sterile, and is a single-use, disposable device. The ClosureFAST catheter function is to provide thermal energy to the desired treatment site via RF heating of the catheter heating element and to relay temperature back to the RF generator. The RF generator remains out of the sterile field during use, and is provided non-sterile. The catheter is connected to the RF generator via the attached sterile cable.

Indications

The Closure system is intended for endovascular coagulation of blood vessels in patients with venous reflux.



*see the Revised one*

Contraindications

- Patients with thrombus in the vein segment to be treated.

**CAUTION: THE VEIN WALL MAY BE THINNER IN AN ANEURYSMAL SEGMENT. TO EFFECTIVELY OCCLUDE A VEIN WITH AN ANEURYSMAL SEGMENT, ADDITIONAL TUMESCENT INFILTRATION MAY BE NEEDED OVER THE ANEURYSMAL SEGMENT, AND THE TREATMENT OF THE VEIN SHOULD INCLUDE SEGMENTS PROXIMAL AND DISTAL TO THE ANEURYSMAL SEGMENT.**

**CAUTION: NO DATA EXISTS REGARDING THE USE OF THIS CATHETER IN PATIENTS WITH DOCUMENTED PERIPHERAL ARTERIAL DISEASE. THE SAME CARE SHOULD BE TAKEN IN THE TREATMENT OF PATIENTS WITH SIGNIFICANT PERIPHERAL ARTERIAL DISEASE AS WOULD BE TAKEN WITH A TRADITIONAL VEIN LIGATION AND STRIPPING PROCEDURE.**

Potential Complications

The potential complications include, but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, adjacent nerve injury, skin burn.

**WARNING: TREATMENT OF A VEIN LOCATED NEAR THE SKIN SURFACE MAY RESULT IN A SKIN BURN IF THE SKIN IS NOT PROTECTED WITH FLUID INFILTRATION.**

**WARNING: NERVE INJURY MAY OCCUR FROM THERMAL DAMAGE TO ADJACENT SENSORY NERVES. RISK OF NERVE INJURY MAY BE HIGHER WITH TREATMENT AT OR BELOW THE CALF, OR WITHOUT PERIVENOUS FLUID INFILTRATION.**

CATHETER INSPECTION & PREPARATION

- 1) Inspect outer box for signs of visible damage.
- 2) Remove sterile pouch from box and inspect for damage (i.e., tears, punctures etc.). If pouch is damaged, do not use catheter.
- 3) Peel pouch open from the end closest to handle (chevron).

- 4) Using sterile technique, remove catheter from pouch and chipboard tray.
- 5) Inspect the catheter. **IF THE CATHETER IS DAMAGED, DO NOT USE THE CATHETER.**
- 6) Pass the end of the attached cable out of the sterile field, for later connection to the RF generator.
- 7) Flush disposable accessories with sterile, physiologic saline (0.9% sodium chloride). Flush and fill catheter lumen with sterile, physiologic saline, or, optionally, heparinized saline. Cap the lumen at the end of the catheter. Wipe the outer surface of the catheter with saline or heparinized saline.
- 8) If using a guidewire, refer to the manufacturer's instructions for use. Following removal of the wire, flush catheter lumen with heparinized saline and cap the lumen at the end of the catheter.

**CAUTION: USE OF A FLUSH THROUGH THE CATHETER WHILE THE HEATING ELEMENT IS ACTIVE WILL HEAT THE FLUID COMING OUT OF THE END OF THE CATHETER. AVOID FLUID DELIVERY THROUGH THE CATHETER WHEN TIP OF CATHETER IS NEAR AN AREA THAT SHOULD NOT BE THERMALLY COGULATED.**

#### GENERATOR SET-UP & OPERATION

**Note: Refer to the RFGPlus RF generator Operator's Manual.**

- 1) Plug in RF generator.
- 2) Turn power "ON" using toggle switch on rear panel.
- 3) Confirm Software version on screen – should be version 3.0 or greater.
- 4) Connect the catheter cable to the RF generator.
- 5) The temperature range for the ClosureFAST catheter is: 85-120°C. Reference the RF generator Operator's Manual for instructions on changing the settings, if desired.

Note: The default settings will not be displayed until a catheter is connected to the RF generator. Default settings may be adjusted according to physician preference.

## PATIENT PREPARATION AND TREATMENT

- 1) If local anesthetic is employed, administer local anesthetic at the vein access site. Mild sedation may also be given.

Note: Venospasm may hinder the ability to access the target vein. Factors which may induce venospasm, such as certain drugs, a cold environment or patient anxiety, should be avoided.

- 2) Position the patient for vein access. Lowering the patient's legs below the level of the heart will increase vein diameter, which may facilitate vein access. For treatment, positioning the patient's legs horizontal or preferably above the level of the heart will assist in reducing vein diameter and reduce venous filling prior to treatment.
- 3) Access the vein to be treated via a percutaneous stick using an 18G thin-walled or 19G ultra thin-walled needle or via a small cut-down.
- 4) Prepare and place introducer sheath per manufacturer instructions for use.

Insert the ClosureFAST catheter into the introducer sheath and advance the catheter tip to the point where treatment will begin. Catheter navigation to the treatment site can be performed using ultrasound guidance, palpation, or with a guidewire. **CAUTION: DO NOT ADVANCE THE CATHETER AND/OR THE GUIDEWIRE AGAINST RESISTANCE, OR VEIN PERFORATION MAY OCCUR.**

- 5) If local anesthesia is employed, administer local anesthetic, preferably, perivenous tumescent anesthesia along the vein segment to be treated.

Note: When the vein is located near the skin surface, a sufficient subcutaneous distance between the vein and skin should be created by tumescent infiltration of saline or dilute local anesthetic solution.

- 6) Use tumescent infiltration of dilute local anesthetic or saline into the perivascular space to create a circumferential fluid layer around the vessel to be treated. Use sufficient volume to exsanguinate and compress the vein to achieve apposition of the catheter heating element and the vein wall.
- 7) Place the patient in the Trendelenburg position so that the leg is above the heart to facilitate vein collapse, apposition, and exsanguination.
- 8) While maintaining catheter tip position, partially withdraw the introducer sheath until the sheath hub and catheter index line are aligned. Secure sheath to skin.
- 9) Prior to the first RF energy delivery, verify the catheter tip positioning using ultrasound.

**WARNING: DO NOT TREAT WITH THE HEATING ELEMENT IN THE DEEP VENOUS SYSTEM.**

- 10) Create firm contact between the vein wall and the entire catheter heating element by ensuring the segment to be treated is compressed prior to energy delivery. Also, create a near-bloodless field for the catheter with no blood flow past the heating element. To accomplish this, perivenous tumescent infiltration is recommended as described in step 6 in addition to two or more of the following steps:

- ◆ External compression along the full length of the heating element.
- ◆ Tightly wrap an Esmark bandage over the limb. This wrap may not be necessary if a sufficient volume of tumescent infiltration is used to exsanguinate the vein and obtain apposition of the vein wall and catheter heating element.
- ◆ Further positioning of the legs of the patient above the heart to facilitate vein collapse, apposition and exsanguination.

**CAUTION: FAILURE TO COMPRESS THE VEIN ONTO THE FULL LENGTH OF THE HEATING ELEMENT MAY RESULT IN INCONSISTENT EFFECTIVENESS AND/OR POSSIBLE CATHETER FAILURE.**

- 11) Enable RF energy delivery by pressing the "RF POWER" button on the RF generator, which will cause the RF Power button to start blinking. If the "RF POWER" button does not light or start blinking, observe any displayed error message and respond. Refer to the RF generator Operator's Manual for further detail.

- 12) Initiate RF energy delivery by pressing the optional "START/STOP" button on the catheter handle, or by pressing the "START RF" button below the screen on the RF generator. Energy delivery can be turned off by rpressing the "START/STOP" button on the catheter handle again, or by pressing the "START RF" button on the RF generator.

Note: If the set temperature is not reached within 5 seconds after RF energy delivery initiation, there may be flow within the vein that is cooling the treatment segment. Terminate RF energy delivery, verify effectiveness of flow occlusion and proper tip position, correct as necessary, and re-initiate treatment of the segment.

Note: Continuous temperature readings below the set temperature may result in incomplete treatment. If this occurs, stop the treatment and reconfirm vessel apposition to the catheter heating element and absence of blood flow in the vessel segment to be treated. Apply more firm external compression if needed and retreat the segment.

- 13) After the treatment time interval, RF energy delivery will terminate automatically. Note: During treatment, RF energy delivery can be stopped if necessary by pressing either the optional "START/STOP" button on the catheter handle, the "STOP RF" button below the screen on the RF generator or the "RF POWER" button on the RF generator.
- 14) RF energy delivery may be repeated in a given vein segment at the physician's option.

**CAUTION: DO NOT READVANCE CATHETER THROUGH AN ACUTELY TREATED VEIN SEGMENT.**

- 15) Quickly withdraw the catheter until the next visible treatment index line is aligned with the hub of the sheath. Note: Some friction between the vein wall and catheter after a heating cycle is normal and may be noticed while withdrawing the catheter.
- 16) Treat the next vein segment according to steps 10 through 15 above, repeating this sequence until all segments are treated. Diagonal lines on the outside of the sheath indicate the last full treatment segment when they are fully visible.
- 17) Confirm the introducer sheath is in the vein before last treatment. Avoid treatment with the heating element inside the sheath.
- 18) Evaluate the treated vein segments with ultrasound to determine the treatment outcome.
- 19) After treatment, disable RF energy delivery by pressing the "RF POWER" button on the RF generator, withdraw the catheter, remove the external compression, and obtain hemostasis at the access site.

## **FOLLOW-UP CARE**

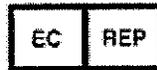
- 1) Instruct patient to ambulate frequently and refrain from strenuous activities or heavy lifting for several days.
- 2) Post-operative compression for at least 1 week is recommended.
- 3) Follow-up examination within 72 hours should include an assessment to ensure that there is no thrombus extension into deep veins.

## PRECAUTIONS

- Store in a dry, cool place.
- Do not use catheter if package is opened or damaged, as sterility is not guaranteed.
- Do not bend catheter into a tight radius. Kinking of the shaft may damage the catheter.
- To prevent damage to the guidewire, ensure that the guidewire does not protrude from the catheter tip when inserting catheter into vein.
- Do not advance catheter and/or guidewire against resistance.
- Do not deliver RF energy with the heating element (tip) of the catheter within the introducer sheath or outside the body.
- Use the Closure*FAST* catheter only with the VNUS RFG*Plus* RF generator.
- Treatment of a vein located close to the skin surface may result in a skin burn if the skin is not protected with fluid infiltration.
- Nerve injury may occur from thermal damage to adjacent nerves. Risk of nerve injury may be higher with treatment at or below the calf or without perivenous fluid infiltration.



**Manufacturer:**  
**VNUS Medical Technologies, Inc.**  
5799 Fontanoso Way  
San Jose, CA 95138 U.S.A.  
Tel: +1-408-360-7200  
Fax: +1-408-365-8480  
www.vnus.com

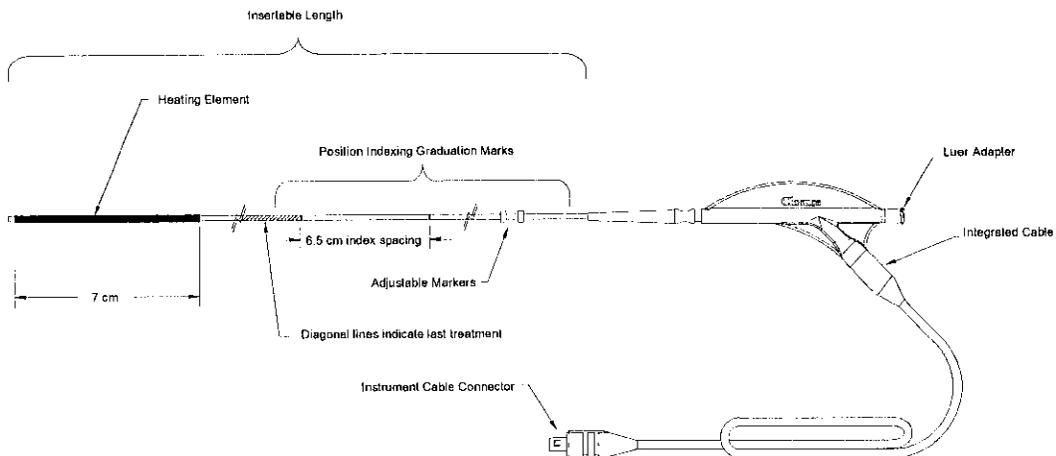


**Authorized Representative:**  
**VNUS Medical Technologies GmbH**  
Marktstrasse 2  
D-71384 Weinstadt  
Germany  
Tel: +49 7151-6046008  
Fax: +49 7151-6046010

One or more of the following patents may apply: 6,237,606; 6,258,084; 6,322,559; 6,638,273; 6,752,803; 6,769,433; and other U.S. and international applications pending.

VNUS, Closure, VNUS Closure, ClosureFAST and RFGPlus are trademarks or registered trademarks of VNUS Medical Technologies in the U. S. and other countries.

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\*Model with START/STOP switch not shown

## Appendix: F

# Biocompatibility Test Reports

























































































































































































































































































From: Reviewer(s) - Name(s) GEORGE J. MATTAMAL

Subject: 510(k) Number K061373

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.)

SE

- 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

GEI + class II  
[CFR 878.4400]

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: 79 GEI + class II

Additional Product Code(s) with panel (optional): subject 79 GEI + class II

Review: [Signature] G5DB 7/31/06  
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 7/31/06  
 (Division Director) (Date)

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 061373

Reviewer: GEORGE J. MATTAMAL

Division/Branch: GSDB / DGRND

Device Name: VNUS Closure Fast Camera

Product To Which Compared (510(K) Number If Known): K030557, K004063

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>		If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>		If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>		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?	<input checked="" type="checkbox"/>		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	<input checked="" type="checkbox"/>		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.

**MEMO TO THE RECORD  
510(k) REVIEW  
K061373**

**DATE:** July 31, 2006  
**FROM:** Polymer Chemist

**OFFICE:** HFZ-410  
**DIVISION:** DGRND/GSDB

**DEVICE NAME:** VNUS Closure® *FAST*™ catheter  
(Catheters, RF Generator, & the Instrument Cable)

**COMPANY NAME:** VNUS Medical Technologies, Inc.

**CONTACT:** Ms. Carelle L. Karimimanesh,  
(Tel. 408-360-7261 & Fax. 408-365-8480)

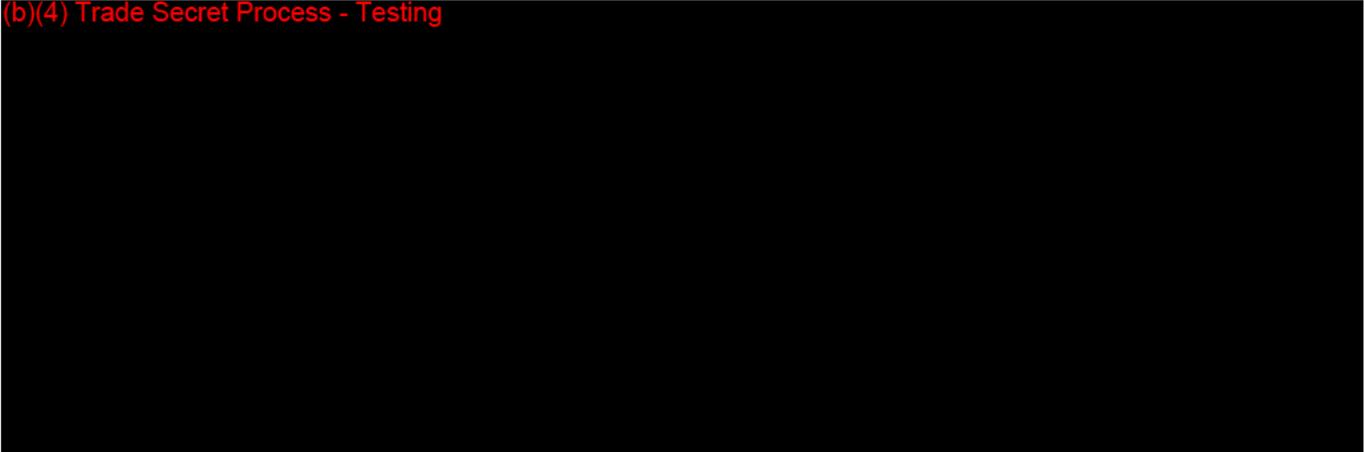
POB  
7/31

---

**BACKGROUND:** The **sole purpose** of the subject K061373 submission is that the sponsor intends to market their previously cleared predicate device, the VNUS® Closure System (K030557) with **several minor device modification changes**. Other than this, the subject and predicate devices employ the same principle, such as endovascular temperature-controlled vein wall heating and collagen denaturation, to achieve durable vessel ablation, and uses the same RF generator (RFG Plus) to power the heating element.

**DEVICE DESCRIPTION and PERFORMANCE:** The subject device, like its predicate devices, in particular to VNUS® Closure Coagulation System (K033557) and their own other VENUS Closure System (K972541, K982816, K004063), is a typical electrosurgical bipolar unit, which consists of an electrosurgical generator and standard accessories such as 1) Standard Instrument cable and 2) a standard sterile, single use modified (probes) catheters. The catheter's function is to coagulate blood vessels by delivering RF energy to a heating element on catheter that is positioned at a desired treatment site. The catheter relays temperature to the FR generator. The generator measures temperature, impedance and delivered power. The minor device modification changes to the catheter in design and construction as compared with the predicate catheter will be the following:

(b)(4) Trade Secret Process - Testing



Other than this, the subject Closure FAST catheter is used with the subject RF generator, Model RFG2, which is a previously cleared predicate K040638 generator. The compatibility of the RF generator with modified catheters has been verified. RF Generator software controls the overall operation and the software used in the subject VNUS RF generator is validated per programs which are based upon the U.S. FDA Reviewer's Guidance for Computer Controlled Medical Devices, and it has been found to be a **moderate level of concern** for the software.

The sponsor has provided a comprehensive comparison table listing the similarities and differences between the subject modified Vessel coagulating system comparing to the predicate VNUS™ Closure™ System (K033547, K982816, K003092 and K030557), in terms of indications for use, bipolar operation, maximum power delivery, temperature range power set, treatment temperature, total energy display, frequency, probe materials, probe packaging, instrument cable, etc. The function, intended use and application of the subject device are very similar to their own predicate VNUS™ Closure™ System, particular to K033547 device.

The sponsor has performed a battery of performance testing on the device including the electrosurgical testing on the generator. Specifically, the subject generator conforms to the EN 60601-2-2, Medical electrical equipment-Part 2: Particular requirements for the safety of high frequency surgical equipment. Also the sponsor has performed in accordance with ISO 14971, risk analysis of the device in accordance with Medical devices- Application of risk management to medical devices (FMEA). Additionally, during the design and development of the subject device and its components in particular to verify dimensional, functional, and electrical safety testing, the sponsors have conducted a battery of functional performance testing to evaluate the performance of the subject disposable VNUS Vessel and Tissue Coagulation devices at different stages of the device development using in conjunction with the VNUS RF Generator and instrument cable.

**ANIMAL TESTING:** The sponsor has performed a series of animal testing (b)(4) Trade Secret Process - Testing  
[Redacted]

This Animal study showed that the subject ClosureFAST catheters (b)(4) Trade Secret Process - Testing  
[Redacted]

**CLINICAL STUDIES:** Chronic Venous insufficiency (CVI) occurs in a relatively large portion of the population and is associated with significant morbidity, high cost of healthcare, loss of productivity and reduced quality of life. The clinical presentations of CVI range from varicose veins through chronic lower extremity pain and edema to venous skin changes and ulceration. The lower extremity venous system is comprised of superficial, deep and perforating veins (PVs).

Endovenous RF Ablation: FDA first cleared the one of the predicate device, the VNUS Closure System in 1999. According to the sponsor, this was the first use of endovenous RF ablation (RFA) for endovenous coagulation of blood vessels in patients with superficial vein reflux. It has been used to treat saphenous reflux as an alternative to vein stripping surgery. To date, more than (b)(4) procedures have been performed. According to the sponsor (b)(4) Trade Secret Process - Testing. The sponsor has provided 17 clinical articles in which these type of procedures have been performed, and one article showed the clinical benefit of RFA versus traditional vein stripping surgery is demonstrated by three randomized studies. In this article, Rautio et al reported significantly less post-operative pain, quantified with a visual analogue scale, and less analgesics needed in the RFA group than in the stripping group.

There is no biocompatibility issues associated with the subject generator since no part of the generator or its accessories come in contact with body fluid or tissue. The non-body contacting Instrument Cables are constructed of (b)(4) Trade Secret Process - Testing. The subject Catheter is constructed of (b)(4) Trade Secret Process - Testing. Additionally, the sponsor has performed the following biocompatibility testing on these materials as required by ISO-10933 Part I: Evaluation and Testing (FDA Modified) for External Communicating Devices, which contact circulating blood for limited duration ( $\leq 24$  hours) including (b)(4) Trade Secret Process - Testing. And these materials passed all the above tests. Also on the modified components of the subject catheter, the sponsor has (b)(4) Trade Secret Process - Testing. There is no safety concern with this proposed device.

**INTENDED USE/INDICATIONS FOR USE (revised):** The subject VNUS Closure® FAST™ catheters (Closure Catheter, RF Generator, & the Instrument Cable), is intended for "endovascular coagulation of blood vessels in patients with superficial vein reflux". This claim is SE r (Chart 3) to their own predicate VNUS™ Closure™ System (K033547, K982816, K003092 and K030557), particular to K030557 device, the VNUS™ Closure™ System.

**PREDICATE DEVICE(S):** The proposed device, VNUS Closure® FAST™ catheters, is SE (Chart 3) in design, technological characteristics (Chart 5), function and intended use to the predicate devices, in particular to their own predicate VNUS™ Closure™ System (K033547, K982816, K003092 and K030557), particular to K033547 device their own predicate VNUS™ Closure™ System (K033547, K982816, K003092 and K030557), particular to K030557 device, the VNUS™ Closure™ System.

**STERILITY, PACKAGING, and LABELING:** The subject generator is exactly same as the cleared their own generator and it will be provided non-sterile, since they do not touch a patient. The subject single use, disposable modified catheter will be provided sterile. The sterilization method will be same as their own predicate device. For example the probe will be sterilized using electron beam (e-beam) irradiation. This process will be validated to achieve a SAL of  $10^{-6}$  and the sterilization validation is in accordance to procedures per AAMI/ISO/11137 and AAMI TIR 27 to substantiate (b)(4) Trade Secret dose. And the recommended cleaning techniques and guidelines for sterilization are included in the Instructions for Use information of the draft labeling for the reusable cable. The sponsor has provided a draft (Instructions for Use) labeling that contains instructions for use statement for bipolar instruments, contraindications, warnings and precautions, specifications, Sterilization instructions, cleaning information, etc., and necessary warning and caution statements as per "the Guidance Document for General Surgical Electrosurgical Devices". And the Draft Labeling for the subject device is found to be satisfactory.

**The SAFETY AND EFFECTIVENESS INFORMATION & TRUTHFUL AND ACCURATE STATEMENT:** The sponsor has provided 1) a revised summary for safety and effectiveness information and 2) a truthful and accurate statement about the device.

**RECOMMENDATION:** The subject device, VNUS Closure® FAST™ catheters, is SE (Chart 7) to its predicate devices, in particular to their own predicate VNUS™ Closure™ System (K033547, K982816, K003092), particular to K033547 device, the VNUS™ Closure™ System. The device is associated with the electrosurgical surgery and categorized as 79 GEI (Electrosurgical device, Cutting & Coagulation & Accessories) and the device is Class II based on 21 CFR 878.4400.

George J. Mattamal 7/31/06  
 George J. Mattamal, Ph.D. (Date)  
 General and Surgery Devices Branch  
 Division of General, Restorative, and Neurological Devices

OK for SE 7/31/06

**CONTACT HISTORY:** The sponsor (Ms. Carelle L. Karimimanesh) was contacted on 7/26/06, 7/27/06, 7/28/06, and 7/31/06 to learn about the device and their own clinical studies on the device, and requested to provide a revised Intended use Statement form, S & E summary form and Draft Labeling of the device to reflex the predicate device. The required information was received on 7/31/06 in e-mail, and the hard copies will follow later.

**Mattamal, George**

**From:** Carelle Karimimanesh [ckarimimanesh@vnus.com]  
**Sent:** Monday, July 31, 2006 11:37 AM  
**To:** Mattamal, George  
**Subject:** K061373 response to question about Intended Use  
**Attachments:** draft changes K061373 27July06.doc

Sorry – here are the corrected pages without highlighting. I sent the hard copies by FedEx on Friday to the Doc Mail Center.

Have you seen any other issues we need to address?

Carelle L. Karimimanesh, RAC  
Director, Regulatory Affairs  
VNUS Medical Technologies, Inc.  
408-360-7261  
www.vnus.com

**From:** Carelle Karimimanesh  
**Sent:** Friday, July 28, 2006 6:31 AM  
**To:** 'Mattamal, George'  
**Subject:** RE: K061373 response to question about Intended Use

I'll get them off to you today. Thanks for the clarification, and have a lovely weekend!

Carelle L. Karimimanesh, RAC  
Director, Regulatory Affairs  
VNUS Medical Technologies, Inc.  
408-360-7261  
www.vnus.com

**From:** Mattamal, George [mailto:george.mattamal@fda.hhs.gov]  
**Sent:** Friday, July 28, 2006 5:34 AM  
**To:** Carelle Karimimanesh  
**Subject:** RE: K061373 response to question about Intended Use

Thanks, Just the corrected pages of what you sent to me earlier. Not the entire submission, only corrected intended use appeared in some pages of the submission. Thanks , George

**George J. Mattamal, Ph.D.**

General Surgery Devices Branch  
DGRND/ODE/CDRH/FDA  
9200 Corporate Blvd  
Rockville, MD 20850  
Tel.# 301-594-1307, ext.138  
Fax # 301-827-4350  
george.mattamal@fda.hhs.gov

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---

**From:** Carelle Karimimanesh [mailto:ckarimimanesh@vnus.com]  
**Sent:** Thursday, July 27, 2006 4:29 PM  
**To:** Mattamal, George  
**Subject:** RE: K061373 response to question about Intended Use

May I just send the four replacement pages or do you need the whole submission?

Carelle L. Karimimanesh, RAC  
Director, Regulatory Affairs  
VNUS Medical Technologies, Inc.  
408-360-7261  
www.vnus.com

---

**From:** Mattamal, George [mailto:george.mattamal@fda.hhs.gov]  
**Sent:** Thursday, July 27, 2006 1:21 PM  
**To:** Carelle Karimimanesh  
**Subject:** RE: K061373 response to question about Intended Use

Thanks Carelle, please send the hard copies of the same to the document center. George

**George J. Mattamal, Ph.D.**

General Surgery Devices Branch  
DGRND/ODE/CDRH/FDA  
9200 Corporate Blvd  
Rockville, MD 20850  
Tel.# 301-594-1307, ext.138  
Fax # 301-827-4350  
george.mattamal@fda.hhs.gov

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---

**From:** Carelle Karimimanesh [mailto:ckarimimanesh@vnus.com]  
**Sent:** Thursday, July 27, 2006 4:01 PM

**To:** Mattamal, George  
**Cc:** Ogden, Neil  
**Subject:** RE: K061373 response to question about Intended Use

Here is the re-corrected draft with changes in highlight.

Carelle L. Karimimanesh, RAC  
Director, Regulatory Affairs  
VNUS Medical Technologies, Inc.  
408-360-7261  
www.vnus.com

---

**From:** Mattamal, George [mailto:george.mattamal@fda.hhs.gov]  
**Sent:** Thursday, July 27, 2006 12:50 PM  
**To:** Carelle Karimimanesh  
**Cc:** Ogden, Neil  
**Subject:** RE: K061373 response to question about Intended Use

Thanks for the information. However, in the intended use statement, Summary of S&E, Draft labeling, Labeling, just like the predicate devices, it **should be** SUPERFICIAL VEIN REFLUX, not **superficial venous reflux**. Please do the correction and send back to us, thanks. **George**

**George J. Mattamal, Ph.D.**

General Surgery Devices Branch  
DGRND/ODE/CDRH/FDA  
9200 Corporate Blvd  
Rockville, MD 20850  
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---

**From:** Carelle Karimimanesh [mailto:ckarimimanesh@vnus.com]  
**Sent:** Thursday, July 27, 2006 2:15 PM  
**To:** Mattamal, George  
**Subject:** K061373 response to question about Intended Use

Dear Dr. Mattamal,

It was very nice chatting with you this morning. I have concurrence with management here at VNUS that we will restore the Intended Use statement of the predicate device, that is, we will apply the word "superficial" to the reference to venous reflux in our ClosureFAST K061373 submission. Accordingly, I am attaching updated drafts(shown highlighted) of the four

instances I believe this occurs in our submission: pages 2-1, B-2, C-2, and E-3.

Upon confirmation from you that these changes are acceptable, I will be happy to transmit hardcopies of these updated pages to replace the existing pages in our submission. If possible, I would prefer to send these by facsimile. If that is acceptable, please provide your facsimile number. If not, I believe I should send them through the Document Mail Center.

We appreciate your diligence and attention to our submission.

Very kind regards,  
Carelle

Carelle L. Karimimanesh, RAC  
Director, Regulatory Affairs  
VNUS Medical Technologies, Inc.  
408-360-7261  
[www.vnus.com](http://www.vnus.com)

## **II. Intended Use/Proposed Labeling**

### **A. Statement of Intended Use**

The ClosureFAST™ catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

A separate Statement of Intended Use is provided in **Appendix B**.

### **B. Device Labeling**

Product labels and instructions for use are contained in **Appendices D and E**, respectively.

### **C. Advertisements and Promotional Literature**

Advertisement and promotional literature for this device has not been drafted. Future advertisement and promotional literature claims will not exceed stated label claims without appropriate data, documentation and regulatory process.

**Mattamal, George**

**From:** Carelle Karimimanesh [ckarimimanesh@vnus.com]  
**Sent:** Monday, July 31, 2006 3:00 PM  
**To:** Mattamal, George  
**Subject:** K061373 response to Statement of Use reformatting  
**Attachments:** CDRH concurrence page 31July06.doc

Hi, Dr. Mattamal,

Thanks for your patience!

Attached is an updated format for the Statement of Use. Please let me know if it is acceptable. If it is, shall I send it to the Doc Mail Center or could you accept this one page as a fax?

Kind regards,  
Carelle

Carelle L. Karimimanesh, RAC  
Director, Regulatory Affairs  
VNUS Medical Technologies, Inc.  
408-360-7261  
www.vnus.com

Device Name: VNUS® ClosureFAST™ Catheter

510(k) Number: K061373

---

**Indications for Use:**

The VNUS® ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

✓

---

**Prescription Use:**  
(21 CFR §801 Subpart D)

or

---

**Over the Counter Use:**  
(21 CFR §801 Subpart C)

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

---

**CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)**

---

K061373  
**510 (k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: 15 May 2006

510(k) number: \_\_\_\_\_

**Applicant Information:**

VNUS Medical Technologies, Inc.  
5799 Fontanoso Way  
San Jose, CA 95138

Contact Person: Carelle Karimimanesh  
Phone Number: (408) 360-7261  
Fax Number: (408) 365-8480

**Device Information:**

Classification: Class II  
Trade Name: VNUS® ClosureFAST™ Catheter  
Classification Name: Electrosurgical Device (21 CFR §878.4400)

**Equivalent Device:**

The subject device is substantially equivalent in intended use and/or method of operation to the VNUS® ClosurePlus™ Catheter (K030557).

The technological characteristics and principals of operation of the VNUS ClosureFAST catheter are substantially equivalent to the noted predicate device. Both devices rely on the delivery of RF energy to an intravascular catheter that heats a blood vessel to a specific temperature to achieve the intended use.

**Intended Use:**

The VNUS® ClosureFAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

**Test Results:**

*Performance*

Results of *in vitro* testing demonstrate that the VNUS ClosureFAST catheter is substantially equivalent to the predicate device effective for its intended function.

*Biocompatibility*

The materials used in the VNUS ClosureFAST Catheters have been shown to be biocompatible.

**Summary:**

Based on the intended use, product performance, and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

<b>Catheter Model</b>	<b>CF7-7-60</b>	<b>CF7-7-100</b>
Introducer Sheath (Minimum ID size)	7F (2.33mm)	7F (2.33mm)
Insertable Length (cm)	60cm	100cm
Heating Element Diameter	2.25mm	2.25mm
Heating Element Length	7cm	7cm

### **Device Description**

The VNUS Closure system consists of two main components: The ClosureFAST™ catheter and the RFGPlus RF generator. The ClosureFAST catheter is provided sterile, and is a single-use, disposable device. The ClosureFAST catheter function is to provide thermal energy to the desired treatment site via RF heating of the catheter heating element and to relay temperature back to the RF generator. The RF generator remains out of the sterile field during use, and is provided non-sterile. The catheter is connected to the RF generator via the attached sterile cable.

#### Indications

The Closure system is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

#### Contraindications

- Patients with thrombus in the vein segment to be treated.

**CAUTION: THE VEIN WALL MAY BE THINNER IN AN ANEURYSMAL SEGMENT. TO EFFECTIVELY OCCLUDE A VEIN WITH AN ANEURYSMAL SEGMENT, ADDITIONAL TUMESCENT INFILTRATION MAY BE NEEDED OVER THE ANEURYSMAL SEGMENT, AND THE TREATMENT OF THE VEIN SHOULD INCLUDE SEGMENTS PROXIMAL AND DISTAL TO THE ANEURYSMAL SEGMENT.**

**CAUTION: NO DATA EXISTS REGARDING THE USE OF THIS CATHETER IN PATIENTS WITH DOCUMENTED PERIPHERAL ARTERIAL DISEASE. THE SAME CARE SHOULD BE TAKEN IN THE TREATMENT OF PATIENTS WITH SIGNIFICANT PERIPHERAL ARTERIAL DISEASE AS WOULD BE TAKEN WITH A TRADITIONAL VEIN LIGATION AND STRIPPING PROCEDURE.**

#### Potential Complications

The potential complications include, but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, adjacent nerve injury, skin burn.

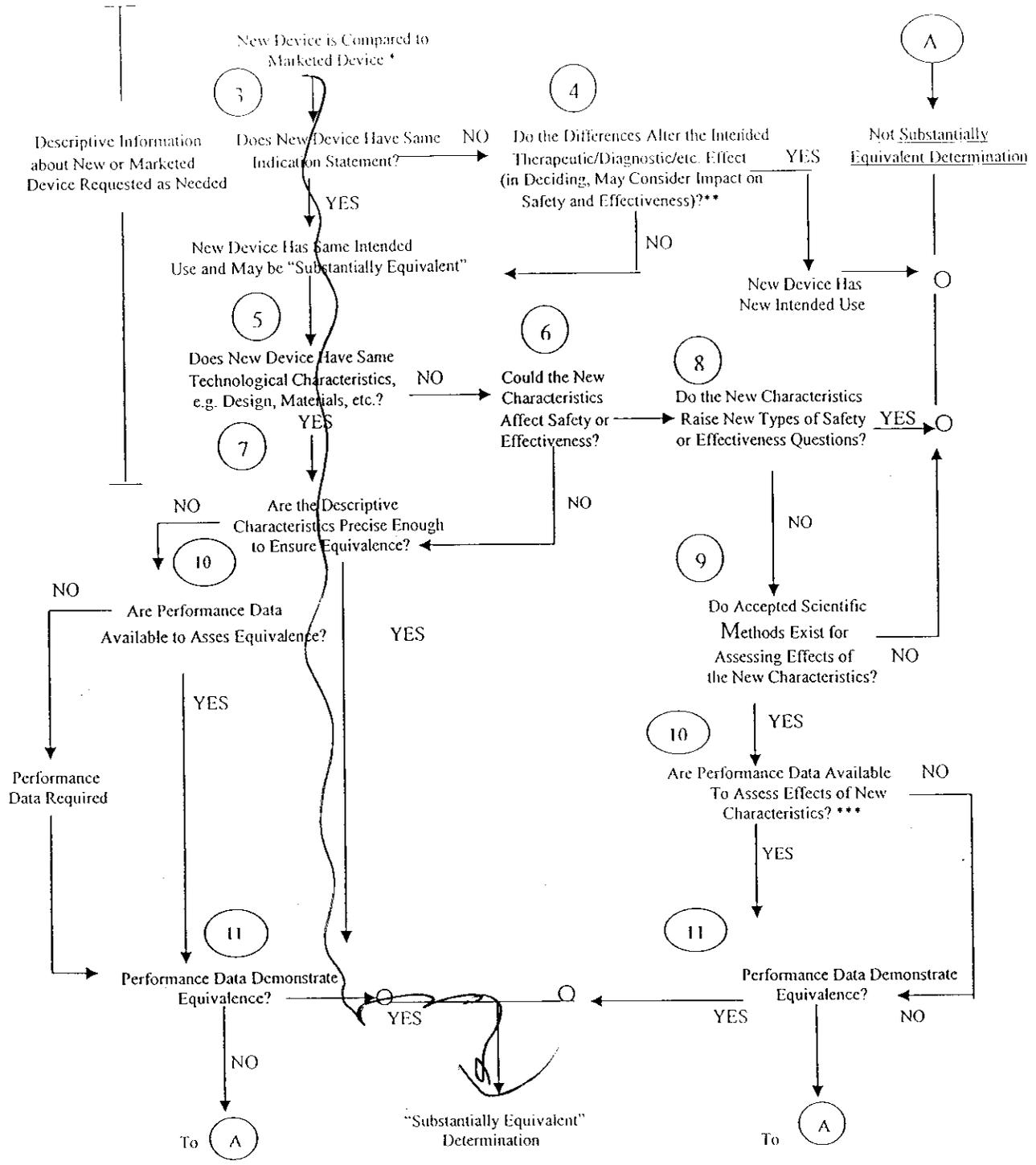
**WARNING: TREATMENT OF A VEIN LOCATED NEAR THE SKIN SURFACE MAY RESULT IN A SKIN BURN IF THE SKIN IS NOT PROTECTED WITH FLUID INFILTRATION.**

**WARNING: NERVE INJURY MAY OCCUR FROM THERMAL DAMAGE TO ADJACENT SENSORY NERVES. RISK OF NERVE INJURY MAY BE HIGHER WITH TREATMENT AT OR BELOW THE CALF, OR WITHOUT PERIVENOUS FLUID INFILTRATION.**

#### CATHETER INSPECTION & PREPARATION

- 1) Inspect outer box for signs of visible damage.
- 2) Remove sterile pouch from box and inspect for damage (i.e., tears, punctures etc.). If pouch is damaged, do not use catheter.

## 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.