



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 2008

Vascular Technology, Inc.
c/o Mr. David L. Regan
Vice President – Sales
12 Murphy Drive
Nashua, NH 03062

Re: K082870
VTI Intraoperative Doppler Systems
Regulation Number: 21 CFR 870.2100
Regulation Name: Flowmeter, Blood Cardiovascular
Regulatory Class: Class II (two)
Product Code: DPW
Dated: September 22, 2008
Received: September 29, 2008

Dear Mr. Regan:

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

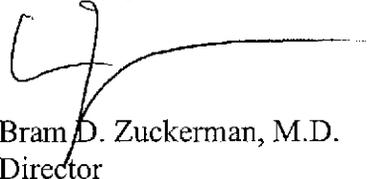
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Page 2 – Mr. David L. Regan

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

Attachment 2 - Indications for Use

510(k) Number (if known): K082870

Device Name: VTI Intraoperative Doppler Systems

Indications for Use:

The VTI Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow.

Indications for Use form filed with the FDA for the VTI Doppler Probes lists the clinical applications as Intraoperative (microvascular and vascular), Intraoperative Neurological, Transesophageal, Transrectal, Laparoscopic and Peripheral Vascular.

Prescription Use

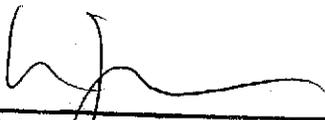
OR

Over-The-Counter-Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082870



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Vascular Technology, Inc.
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Sincerely yours,



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

Enclosure

Attachment 2 - Indications for Use

510(k) Number (if known): K082870

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Prescription Use

OR

Over-The-Counter-Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082870



October 01, 2008

VASCULAR TECHNOLOGY INCORPORATED
12 MURPHY DR.
NASHUA, NEW HAMPSHIRE 03062
UNITED STATES
ATTN: DAVID L. REGAN

510k Number: K082870
Received: 9/30/2008
Product: VTI INTRAOPERATIVE D

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

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Records Processed under FOIA Request # 2015-3943: Released by CDRH on 9-10-2015
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at 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).

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

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

September 30, 2008

VASCULAR TECHNOLOGY INCORPORATED
12 MURPHY DR.
NASHUA, NEW HAMPSHIRE 03062
UNITED STATES
ATTN: DAVID L. REGAN

510k Number: K082870
Received: 9/29/2008
User Fee ID Number: 6038584
Product: VTI INTRAOPERATIVE DOPPLE

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 all future correspondence that relates to this submission. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. Please send a check to one of the addresses listed below:

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

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

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

Records Processed under FOIA Request # 2015-3943; Released by CDRH on 9-10-2015
Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Pre-market Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K082870

Form Approved: OMB No. (9110-511) Expiration Date: January 31, 2010. See Instructions for OMB Statement

| | | | |
|---|--|---|--|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET | | PAYMENT IDENTIFICATION NUMBER Write the Payment Identification number | |
| A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html | | | |
| 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) VASCULAR TECHNOLOGY 12 Murphy Drive Nashua NH 03062 US | | 2. CONTACT NAME David Regan 2.1 E-MAIL ADDRESS dregan@vti-online.com 2.2 TELEPHONE NUMBER (include Area code) 603-5949700 22 2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-null | |
| 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 510662979 | | | |
| 3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma) | | | |
| Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice | | 3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) | |
| 4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA 4.1 If Yes, please enter your Small Business Decision Number: SBD088327 <input type="checkbox"/> NO, I am not a small business | | | |
| 5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially | | | |
| 6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | | |
| (b) (4) | | AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION | |
| | | 22-Sep-2008 | |

David L. Regan
Close Window Print Cover sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

| | | |
|--------------------|----------------------------|---|
| Date of Submission | User Fee Payment ID Number | FDA Submission Document Number (if known) |
|--------------------|----------------------------|---|

SECTION A TYPE OF SUBMISSION

| | | | | |
|--|--|---|---|--|
| <p>PMA</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>PMA & HDE Supplement</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>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP | <p>510(k)</p> <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party | <p>Meeting</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>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement | <p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment | <p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | <p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | <p>Other Submission</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 Vascular Technology | Establishment Registration Number (if known) 1221072 | | |
| Division Name (if applicable) | Phone Number (including area code) (603) 594-9700 | | |
| Street Address 12 Murphy Drive | FAX Number (including area code) (603) 594-0092 | | |
| City Nashua | State / Province NH | ZIP/Postal Code 03062 | Country USA |
| Contact Name David Regan | | | |
| Contact Title Vice President | Contact E-mail Address dregan@vti-online.com | | |

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

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

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

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

SECTION D2

REASON FOR APPLICATION - IDE

| | | |
|--|---|---|
| <input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access | <input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor | <input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing |
| <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final | | |
| <input type="checkbox"/> Other Reason (<i>specify</i>): | | |

SECTION D3

REASON FOR SUBMISSION - 510(k)

| | | |
|--|---|---|
| <input type="checkbox"/> New Device | <input type="checkbox"/> Additional or Expanded Indications | <input type="checkbox"/> Change in Technology |
| <input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Change of power source | | |

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 | DPW | 2 | | 3 | |
| - | | 6 | | 7 | |
| | | | | <input type="checkbox"/> 510 (k) summary attached <input checked="" 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 | K860651/A | VTI Microvascular Doppler | Vascular Technology |
| 2 | K031091 | VTI Gated Doppler | Vascular Technology |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

| | Trade or Proprietary or Model Name for This Device | Model Number |
|---|--|--------------|
| 1 | VTI 20 MHZ Transciever A/C | 108400-A/C |
| 2 | VTI 20 MHZ Gated Transciever A/C | 108700-A/C |
| 3 | VTI 8 MHZ Transciever A/C | 108910-A/C |
| 4 | VTI 8 MHZ Gated Transciever A/C | 108710-A/C |
| 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 DPW | C.F.R. Section (if applicable) 21 CFR 870.2100 | Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified |
| Classification Panel Division of Cardiovascular Devices | | |

Indications (from labeling)
VTI Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow.

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

| SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION | | | |
|---|---|--|---|
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | Facility Establishment Identifier (FEI) Number 510662979 | <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer | <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler |
| Company / Institution Name Vascular Technology | | Establishment Registration Number 1221072 | |
| Division Name (if applicable) | | Phone Number (including area code) (603) 594-9700 | |
| Street Address 12 Murphy Drive | | FAX Number (including area code) (603) 594-0092 | |
| City Nashua | State / Province NH | ZIP/Postal Code 03062 | Country USA |
| Contact Name David Regan | Contact Title Vice President | Contact E-mail Address dregan@vti-online.com | |
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | Facility Establishment Identifier (FEI) Number | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer | <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler |
| Company / Institution Name | | Establishment Registration Number | |
| Division Name (if applicable) | | Phone Number (including area code) () | |
| Street Address | | FAX Number (including area code) () | |
| City | State / Province | ZIP/Postal Code | Country |
| Contact Name | Contact Title | Contact E-mail Address | |
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | Facility Establishment Identifier (FEI) Number | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer | <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler |
| Company / Institution Name | | Establishment Registration Number | |
| Division Name (if applicable) | | Phone Number (including area code) () | |
| Street Address | | FAX Number (including area code) () | |
| City | State / Province | ZIP/Postal Code | Country |
| Contact Name | Contact Title | Contact E-mail Address | |

SECTION I

UTILIZATION OF STANDARDS

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

| | Standards No. | Standards Organization | Standards Title | Version | Date |
|---|---------------|------------------------|---|-------------|------------|
| 1 | EN ISO 13485 | EN ISO | 2003 Quality systems - Medical devices - Particular requirements | 2nd edition | 07/15/2003 |
| 2 | EN ISO 14971 | EN ISO | Medical devices - Application of risk management to medical devices | E | 04/01/2007 |
| 3 | EN 980 | EN ISO | Graphical symbols for use in the labeling of medical devices | E | 04/01/2003 |
| 4 | EN 1041 | EN ISO | Information supplied by the manufacturer with medical devices | | 02/01/1998 |
| 5 | EN 60601-1-1 | EN ISO | Medical electrical equipment --Part 1-1: General requirements for safety | Issue 1 | 10/01/1997 |
| 6 | EN 60601-1-2 | EN ISO | Medical electrical equipment --Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and test | 3rd Edition | 03/01/2007 |
| 7 | EN 60601-2-37 | EN ISO | Medical electrical equipment -- , Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment | Edition 1.1 | 10/01/2004 |

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

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Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(K)
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Medical electrical equipment --Part 1: General requirements for safety

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 5-4

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of the standard?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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⁶ The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
MEDICAL ELECTRICAL EQUIPMENT --PART 1: GENERAL REQUIREMENTS FOR SAFETY

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|-------------------------|--|
| 19.201.2 | Patient Leakage Current | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*
Type CF Applied Parts

DESCRIPTION
Allows lowest level of patient leakage

JUSTIFICATION
Strictest requirement

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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1350 Piccard Drive
Rockville, MD 20850

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Food and Drug Administration
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Medical devices – Application of risk management to medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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Is there an FDA guidance ⁶ that is associated with this standard?
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Title of guidance: _____

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Medical electrical equipment --Part I-1: General requirements for safety

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 5-27

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
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 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

MEDICAL ELECTRICAL EQUIPMENT --PART 1-2: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS.

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| All | All | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*

Device was tested a Class A, Group I, non-life supporting

DESCRIPTION

Device was tested a Class A, Group I, non-life supporting where appropriate

JUSTIFICATION

Device does not support life and is for use in a hospital environment

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Medical electrical equipment -- Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, Amendment A1:2005 to EN 60601-2-37:2001

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 12-164

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

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If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Medical electrical equipment --Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 5-28

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

| | | |
|----------------|---------------|---|
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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Vascular Technology

12 Murphy Drive
Nashua, NH 03062

TOLL FREE: 800-550-0856
TEL: 603-594-9700
FAX: 603-594-0092

www.vti-online.com
E-MAIL: info@vti-online.com

Received
SEP 29 2008
FDA CDRH DMC

September 22, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, HFZ-401
Rockville, MD 20850 USA

CONTENTS: SPECIAL 510(k) PREMARKET NOTIFICATION

Re: Premarket Notification for Vascular Technology, Inc. Family of Doppler Models.

Gentlemen:

Pursuant to the requirements of section 510(k) of the Food, Drug, and Cosmetic Act, enclosed is notification that Vascular Technology, Incorporated intends to market our family of modified VTI 20 MHz and 8 MHz Intraoperative Doppler models.

Based on the Code of Federal Regulations, section (CFR 807.81(a)(3) and the FDA guidance document titled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" VTI believes the modifications to our device requires a submission of a new notification. Since this device has been cleared under the 510(k) process and the modification does not affect the intended use of the device or alter the fundamental scientific technology of the device, VTI believes that the modifications meet the criteria set forth to be accepted and cleared under a Special 510(k).

1022

The family of Doppler transceivers is of the same generic device type and the impact of the modifications on each of the devices is identical and can be efficiently assessed during one review. The family of Doppler transceivers consists of four (4) models - VTI 20 MHz Microvascular Doppler, VTI 20 MHz Gated Microvascular Doppler, VTI 8 MHz Surgical Doppler, and VTI 8 MHz Gated Surgical Doppler. All models use the same circuitry design and the same printed circuit boards. There are a few select components different between the 8 and 20 MHz System to allow for the different frequency

(b) (4)

(b) (4)

With the exception of having a (b) (4) the option to operate from an external A/C to D/C power converter, and having (b) (4) these models are identical in fit, form, function, materials, intended use and fundamental scientific technology to the part number 108700 VTI Gated 20 MHz Doppler, currently marketed under 510(k) number K031091. The A/C to D/C power converter employed is an off the shelf model, that has been tested, both alone and as system with our device, and found to be fully compliant for medical use by a third party test agency.

These Doppler models will be used in conjunction with existing VTI 20 and 8 MHz Doppler probes which have not been modified and are covered by the original submissions.

These modifications to an existing product were completed under full design control. Where appropriate, third party test agencies were utilized to show compliance. These models are sold non-sterile and are not intended to be sterilized.

The proposed device VTI intends to market is substantially equivalent to the VTI 20 MHz Gated Doppler, part number 108700 which is marketed under 510(k) Number K031091. The intended use and indications are the same for the modified and predicate devices.

The information and data contained in this notification was derived from production devices and is in its final form therefore, this should be considered a final 510(k) submission. Should you have any questions regarding this submission, please contact the undersigned at the above-listed telephone number.

Best regards,



David L. Regan

Vice President – Sales

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DEVICE NAME:

VTI Intraoperative Doppler Systems

COMMON NAME:

Pulsed Doppler

MANUFACTURER'S NAME:

Vascular Technology, Incorporated

Address: 12 Murphy Drive, Nashua, NH 03062

Corresponding Official: David L. Regan Title: Vice President - Sales

Address: 12 Murphy Drive, Nashua, NH 03062

Telephone: (603)-594-9700 FAX: (603)-594-0092

ESTABLISHMENT REGISTRATION NUMBER:

1221072

CLASSIFICATION

Regulatory Class: II

FR Number Product Code

Other: Cardiovascular blood flowmeter 870.2100-DPW

PERFORMANCE STANDARDS

None

SPECIAL CONTROLS:

None

PRESCRIPTION STATUS:

Prescription Device

PREDICATE DEVICE

The proposed device VTI intends to market is substantially equivalent to the VTI 20 MHz Gated Doppler, part number 108700 which is marketed under 510(k) Number K031091

LABELING AND INTENDED USE

Draft labels and Instructions for Use can be found in Attachment 1.

Indications for use, contraindications, warnings, and precautions are clearly stated in the instructions for use.

This includes (but is not limited to):

“ALARA” is not applicable to this device.

“Not intended for fetal use” statement is included in the instructions for use

Acoustic output labeling is found on the Doppler Probe Labeling.

Instruction for care of the device is provided in the instructions for use

Intended Use

The VTI Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow.

The Indications for Use statement can be found in Attachment 2.

GENERAL DEVICE DESCRIPTION

The VTI Intraoperative Doppler Systems are Class II externally D/C powered pulsed Doppler ultrasound systems designed for the evaluation of blood velocity in vessels. The transceiver can also be powered by eight standard AA (LR6) internal alkaline batteries. A Doppler probe, which plugs into the transceiver unit, emits a pulsed ultrasonic signal. A varying audible signal is produced when the probe is placed upon a vessel within which there is flow. The frequency (i.e., pitch) of the signal is proportional to the blood velocity within the vessel. Distinctive tonal patterns are produced which are indicative of the flow pattern in terms of velocity vs. time. The volume of the tone may be adjusted by means of a control on the transceiver. The depth of signal penetration can also be varied using control switches in some models. This allows the user to interrogate vessels which lie at varying depths. A transmitter in

the transceiver periodically drives the ultrasonic transmitting crystal located at the tip of the probe. The ultrasonic waves generated by the crystal travel through the tissue just under the probe tip in a fairly narrow beam. They are then reflected back towards the probe whenever they encounter a boundary between tissues of different densities. During the intervals when the unit is not transmitting, the probe passes any reflected signals that it receives to a receiving circuit. This circuit amplifies the re-turning echoes, compares their frequency to that of the transmitted signal and converts any frequency differences into an audible tone.

The family of Doppler transceivers consists of four (4) models – VTI 20 MHz Microvascular Doppler, VTI 20 MHz Gated Microvascular Doppler, VTI 8 MHz Surgical Doppler, and VTI 8 MHz Gated Surgical Doppler. All models use the same circuitry design and the same printed circuit board. There are a few select components differences between the 8 and 20 MHz System to allow for the different frequency (b) (4)

(b) (4)

The Dimensions of the device are 6.5 in. D X 10 in. W X 3.75 in. H. (165 mm X 254 mm X 101 mm), nom and the weight is 2.6 lb, (1.18 kg), nom.

The effective and safe use of Intraoperative Dopplers is well documented in the medical literature. References to some of this literature are provided below.

- 1) Elami A, Laks H, Merin G. Technique for reoperative median sternotomy in the presence of a patent left internal mammary artery graft. *J Card Surg.* 1994 Mar;9(2):123-7.
- 2) Firsching R, Synowitz HJ, Hanebeck J. Practicability of intraoperative microvascular Doppler sonography in aneurysm surgery. *Minim Invasive Neurosurg.* 2000 Sep;43(3):144-8.
- 3) Gostout CJ. Do we need more technology to reduce recurrence of bleeding from ulcers? *Gastrointest Endosc.* 2000 Sep;52(3):438-40.
- 4) Kohler B, Maier M, Benz C, Riemann JF. Acute ulcer bleeding. A prospective randomized trial to compare Doppler and Forrest classifications in endoscopic diagnosis and therapy. *Dig Dis Sci.* 1997 Jul;42(7):1370-4.
- 5) Loughlin KR, Brooks DC. The use of a Doppler probe in laparoscopic surgery. *J Laparoendosc Surg.* 1992 Jun;2(3):191-4.
- 6) Pelosi MA, Pelosi MA 3rd. Auditory identification of pelvic blood vessels during laparoscopically assisted vaginal hysterectomy. Use of the endoscopic Doppler probe. *J Reprod Med.* 1993 Oct;38(10):771-4.

- 7) Seifert KB, Blackshear WM Jr. Continuous-wave Doppler in the intraoperative assessment of carotid endarterectomy. *J Vasc Surg.* 1985 Nov;2(6):817-20.
- 8) Wong RC, Chak A, Kobayashi K, Isenberg GA, Cooper GS, Carr-Locke DL, Sivak MV Jr. Role of Doppler US in acute peptic ulcer hemorrhage: can it predict failure of endoscopic therapy? *Gastrointest Endosc.* 2000 Sep;52(3):315-21.

(b) (4)

COMPARISON TO THE CLEARED DEVICE

With the exception of having a [REDACTED] having the option to operate from an A/C to D/C power converter, and having [REDACTED] these models are identical in fit, form, function, materials, intended use and fundamental scientific technology to the part number 108700 VTI Gated 20 MHz Doppler, currently marketed under 510(k) number K031091. The A/C to D/C power converter employed is an off-the-shelf model that has been tested both alone and as a system with our device, and found to be fully complaint for medical use by a third party test agency.

These Doppler models will be used in conjunction with a number of existing VTI 20 and 8 MHz Doppler probes which have not been modified and are covered by the original submissions.

COMPARISON TABLE

| | Cleared Device | New Device |
|---------------------|---|---|
| Intended use | The VTI Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow. | The VTI Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow. |
| Indications for use | Indications for Use form filed with the FDA for the VTI Doppler Probes lists the clinical applications as Intraoperative (microvascular and vascular), Intraoperative Neurological, Transesophageal, Transrectal, Laparoscopic and Peripheral Vascular. | Indications for Use form filed with the FDA for the VTI Doppler Probes lists the clinical applications as Intraoperative (microvascular and vascular), Intraoperative Neurological, Transesophageal, Transrectal, Laparoscopic and Peripheral Vascular. |
| Target population | Surgical patients | Surgical patients |

| | | |
|--|---|--|
| Where used (hospital, home, ambulance, etc) | Hospital, outpatient surgery center | Hospital, outpatient surgery center |
| Energy used and/or delivered | 12 volts direct current supplied by eight standard AA (LR6) alkaline batteries. | 12 volts direct current supplied by A/C to D/C converted or by eight standard AA (LR6) alkaline batteries. |
| | (b) (4) | |
| Design | Conventional | Conventional |
| Performance | Meets requirements in "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers". | Meets requirements in "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers". |
| Standards met | See attached | See attached |
| Materials | (b) (4) | |
| Biocompatibility | N/A | N/A |
| Compatibility with the environment and other devices | Tested to Medical electrical equipment --Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests. | Tested to Medical electrical equipment - -Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests. |
| Sterility | N/A | N/A |
| Electrical safety | Tested to Medical electrical equipment --Part 1-1: General requirements for safety | Tested to Medical electrical equipment - -Part 1-1: General requirements for safety |
| Mechanical safety | Tested to Medical electrical equipment --Part 1: General requirements for safety | Tested to Medical electrical equipment - -Part 1: General requirements for safety |
| Chemical safety | N/A | N/A |
| Thermal safety | Tested to Medical electrical equipment -- , Part 2-37: Particular requirements for the safety of ultrasonic medical | Tested to Medical electrical equipment - - , Part 2-37: Particular requirements for the safety of ultrasonic medical |

| | | |
|------------------|--|---|
| | diagnostic and monitoring equipment, Amendment A1:2005 to EN 60601-2-37:2001 | diagnostic and monitoring equipment, Amendment A1:2005 to EN 60601-2-37:2001 |
| Radiation safety | Tested to Medical electrical equipment -- , Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, Amendment A1:2005 to EN 60601-2-37:2001 | Tested to Medical electrical equipment , Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, Amendment A1:2005 to EN 60601-2-37:2001 |

SUBSTANTIALLY EQUIVALENT

The proposed device VTI intends to market is substantially equivalent to the VTI 20 MHz Gated Doppler, part number 108700 which is marketed under 510(k) Number K031091. The intended use and indications are the same for the modified and predicate devices.

SUMMARY OF DESIGN CONTROL ACTIVITY

Design activities, objectives and status were tracked and regularly communicated to appropriate individuals within the company. A checklist was used as a guide to ensure the necessary elements were present.

Market research shows that there is a need for an intraoperative Doppler capable of being powered from a wall outlet.

A Design Plan and Design Schedule was developed that included: an overview of the project, a Product Description, a Definition of Responsibilities, a Reference to any procedures to be used as part of the design process, any Regulatory Requirements and Identification of Project Team Members.

Design Inputs were developed and refined outlining: Safety requirements, Performance and reliability characteristics, Limits and tolerances, Risk analysis,, Electromagnetic compatibility, Compatibility with accessories/auxiliary devices, Compatibility with the environment of intended use, Voluntary standards, Human factors, Labeling/packaging, Statutory and regulatory requirements, Appropriate materials and manufacturing processes, and MDR's/complaints/failures and other historical data.

Three formal design reviews were conducted over the course of the design development.

Design Verification confirmed that the design output met the design input requirements.

Design verification was completed by comparing the modified design with the predicate device design. Testing, including electrical safety testing, electromagnetic compatibility and acoustical power output testing. Design validation to ensure that devices conformed to defined user needs and intended uses included testing of production units under simulated conditions and a risk analysis.

RISK ANALYSIS

Throughout the design process, VTI evaluated the need for risk analysis and maintained records of any risk analyses performed.

The risk analysis attempted to identify risks inherent in the device design as well as potential risks associated with the use and misuse of the device. Risks were reduced or eliminated through the use of design changes, testing, labeling, or manufacturing/quality management. The Risk analysis was performed in accordance with ISO 14971:2000 – Application of Risk Management to Medical Devices. The Risk analysis was documented and included and/or referenced in the design history file.

Since a risk analysis was available for the VTI 20 MHz Gated Doppler, part number 108700, it was used as a base of reference because this device and the modified device are similar. The Risk analysis focused on the modifications that were made and the new hazards that they could introduce.

A list of known or foreseeable hazards (normal, misuse/faulty, situations) associated with the modified device was compiled in the Risk Management file. The new hazards associated with the modified device all centered on electrical isolation and electromagnetic compatibility.

When necessary, risk reduction was undertaken. Risk control measures were identified and used in the following order to reduce risk; safe design, protective measures and information for the user identifying specific actions to be taken. To mitigate risk the modifications were designed around the use of an off the shelf A/C to D/C power converted that was designed (b) (4)

(b) (4)

medical devices. To lessen the risk associated with (b) (4) (b) (4) was added to the design and additional (b) (4) electrical safety testing was added to the final test procedure. A (b) (4)

(b) (4)

After risk controls were implemented the residual risk was evaluated using the criteria defined in the Risk Management Plan. The system was fully tested to the major safety standard for electro-medical devices (IEC 60601 series with the European equivalent of the EN 60601 series). IEC 60601-1 covered all generic requirements including a list of hazards and their tolerable limit of risk. IEC 60601-1-X collateral standard series was used in conjunction with the IEC/EN 60601-1. The cTUVus mark was issued after successful testing against applicable standards.

SUMMARY OF THIRD PARTY TESTING

| Standard | Test Results | Tested By |
|--|--------------|---|
| EN 60601-1:1990 Medical electrical equipment --Part 1: General requirements for safety | Passed | TÜV Rheinland of North America Inc. |
| EN 60601-1-1:2001 Medical electrical equipment --Part 1-1: General requirements for safety, Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-1:2000 | Passed | TÜV Rheinland of North America Inc. |
| EN 60601-1-2:2001 2 nd Edition Medical electrical equipment --Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests. IEC 60601-1-2:2001 | Passed | TÜV Rheinland of North America Inc. |
| EN 60601-2-37:2001, Medical electrical equipment, Part 2-37: Particular requirements for the safety of ultrasonic | Passed | TÜV Rheinland of North America Inc. Sonora Medical Systems |

| | | |
|--|--|--|
| medical diagnostic and monitoring equipment. | | |
|--|--|--|

A declaration of conformity with design controls is included in Attachment 3.

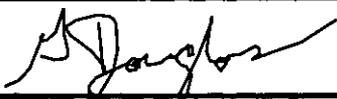
510(k) STATEMENT

A 510(k) Statement for the *VTI Intraoperative Doppler Systems* is included in Attachment 4.

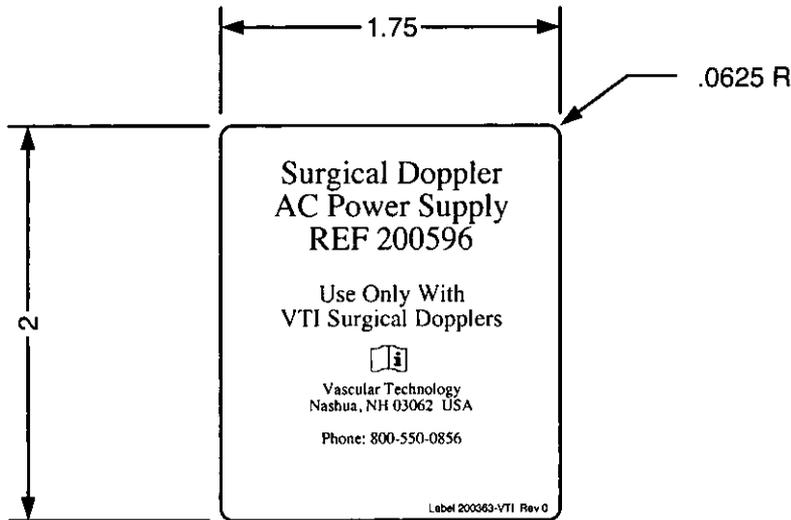
TRUTHFUL AND ACCURATE STATEMENT

A certification of the truthfulness and accuracy is provided in Attachment 5.

ATTACHMENT 1- DRAFT LABELS AND INSTRUCTIONS FOR USE

| | | | | |
|------|---|------|--|---|
| REV. | Records Description: Records Under FOIA Request # 2015-0741, Release by CDRH on 8/10/2016 | DATE | CHECKED | APPROVED |
| 0 | Original issue per ECO 10390 | GD |  |  |

G. Douglas 9/22/2008

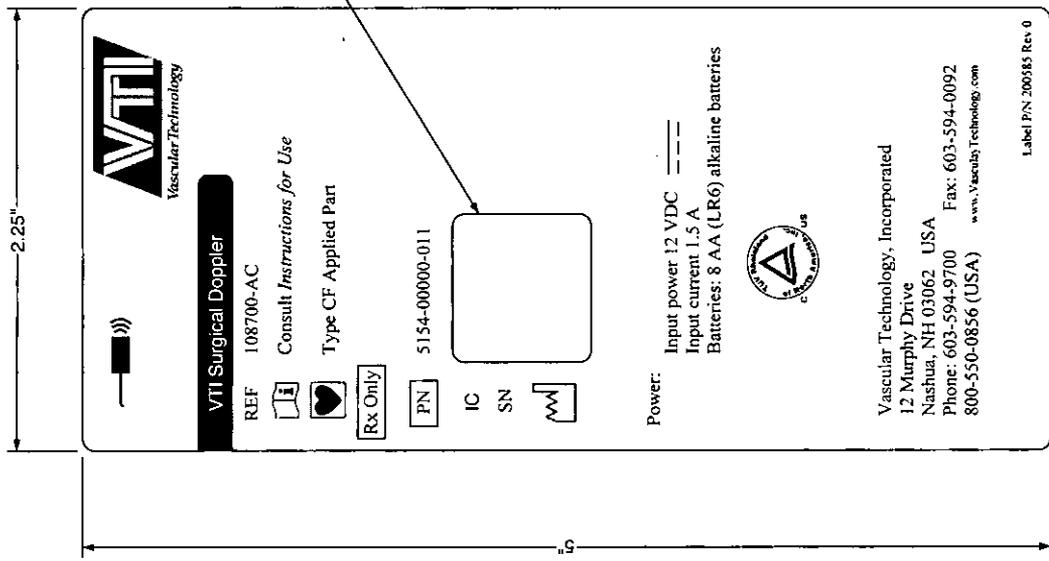


3. SILKSCREEN TEXT WHITE ON A BLACK BACKGROUND.
 2. USE ARTWORK SUPPLIED BY VTI ONLY. DO NOT GENERATE A NEW ARTWORK.
 1. MATERIAL: 5 MIL THICK VELVET LEXAN WITH A 5 MIL THICK PERMANENT ADHESIVE BACKING AND LINER.
- NOTES:

| | | | | | |
|-----------------------------|----------|----------------|------------|---|----------------------------|
| SIZE | A | SCALE | 1:1 |  | <i>Vascular Technology</i> |
| UNLESS OTHERWISE SPECIFIED: | | TOLERANCES | | TITLE | |
| DIMENSIONS IN INCHES | | FRACTION | | LABEL: POWER SUPPLY, VTI | |
| MACHINED FINISH: 63 | | .X ± 1/32 | | | |
| REMOVE ALL BURRS | | .XX ± .1 | | | |
| REMOVE ALL SHARP EDGES. | | .XXX ± .015 | | | |
| DO NOT SCALE DRAWING. | | .XXXX ± .005 | | | |
| | | ANGLES ± .0005 | | SHT 1 OF 1 | |
| | | ± 1/2° | | DWG NO. 200363-VTI | |
| | | | | REV. 0 | |

| REV | DESCRIPTION | DRAWN | CHECKED | ED |
|-----|------------------------------|-------|---------|----|
| 0 | Original issue per ECO 10390 | GD | | |

Gary Douglas 8/22/2009



2. Colors: PRINT TEXT BLACK ON A PMS WARM GRAY 1 C BACKGROUND
ORANGE=PMS 131
GRAY=PMS 429
GREEN=PMS 322

1. MATERIAL: 5MIL THICK VELVET LEXAN WITH A 5 MIL THICK PERMANENT ADHESIVE BACKING AND LINER

NOTES:

| SIZE | C | SCALE | Not to Scale | TITLE |
|--|---|-------|--------------|----------------------------|
| | | | | Vascular Technology |
| UNLESS OTHERWISE SPECIFIED: TOLERANCES | | | | |
| DIMENSIONS IN INCHES | | | | FRACTION ± 1/32 |
| REMOVE ALL BURRS | | | | XX ± .1 |
| REMOVE ALL SHARP EDGES | | | | .XXX ± .015 |
| DO NOT SCALE DRAWING | | | | .XXXX ± .005 |
| | | | | ANGLES ± 1/2° |
| SHT | 1 | OF | 1 | DWG NO. 200585 |
| | | | | REV. 0 |

| REV. | DESCRIPTION | DRAWN | CHECKED | DATE | BY |
|------|--------------------|-------|-------------------------------------|------|-------------------|
| 0 | Rev per ECO 10390. | GD | <input checked="" type="checkbox"/> | | <i>H. Douglas</i> |

G. Douglas 9/22/2008

1.00

Small Radius to Corners

0.62

USE ONLY WITH
200363-VTI POWER SUPPLY

Label P/N 200387-VTI Rev 0

3. DO NOT PRINT BORDER.

2. SILKSCREEN TEXT BLACK ON A PMS WARM GRAY 1 C BACKGROUND.

1. MATERIAL: 5 MIL THICK VELVET LEXAN WITH A 5 MIL THICK PERMANENT ADHESIVE BACKING AND LINER.

| SIZE | SCALE | Not to Scale | TITLE |
|--|-------|--------------|--------------------------------------|
| C | | | Vascular Technology |
| <small>UNLESS OTHERWISE SPECIFIED: TOLERANCES: DIMENSIONS IN INCHES: FRACTION ± 1/32 DECIMAL ± .015 REMOVE ALL BURRS .03 REMOVE ALL SHARP EDGES. DO NOT SCALE DRAWING. ANGLES ± 1/2°</small> | | | LABEL: POWER INPUT |
| | | | SHT 1 OF 1 DWG NO. 200387-VTI REV. 0 |

NOTES:

ATTACHMENT 2 - INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: VTI Intraoperative Doppler Systems

Indications for Use:

The VTI Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow.

Indications for Use form filed with the FDA for the VTI Doppler Probes lists the clinical applications as Intraoperative (microvascular and vascular), Intraoperative Neurological, Transesophageal, Transrectal, Laparoscopic and Peripheral Vascular.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter-Use _____

(Per 21CFR 801.109)

ATTACHMENT 3 - DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

I certify that, in my capacity as Quality Manager of Vascular Technology, the changes to the modified device are in conformance with our design controls procedures and that verification and validation activities were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

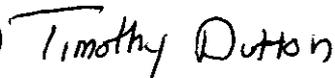
I certify that, the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and that the records are available for review.

(Signature)



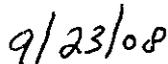
Timothy Dutton

(Typed Name)



September 23, 2008

(Date)



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

*For a new submission, leave the 510(k) number blank.

ATTACHMENT 4 - 510(k) STATEMENT

PREMARKET NOTIFICATION

510(k) STATEMENT

(As Required By 21 CFR 807.93)

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

David L. Regan

(Signature of Certifier)

David L. Regan

(Typed Name)

September 23, 2008

(Date)

09-23-08

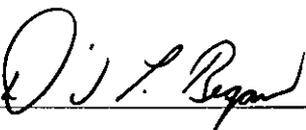
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank

ATTACHMENT 5 - TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Vice President of Sales of *Vascular Technology*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.



(Signature)

David L. Regan

(Typed Name)

September 23, 2008

(Date)

09-23-08

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

*For a new submission, leave the 510(k) number blank.

*ATTACHMENT 6- CERTIFICATION OF COMPLIANCE WITH REQUIREMENTS OF
CLINICALTRAILS.GOV DATA BANK*

Records Processed under FOIA Request # 2015-0040, Released by CDRH on 9-10-2015



Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

*For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

| | |
|---|--|
| 1. NAME OF SPONSOR/APPLICANT/SUBMITTER Vascular Technology | 2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 07/18/2008 |
| 3. ADDRESS (Number, Street, State, and ZIP Code) 12 Murphy Drive Nashua, NH 03062 | 4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) (603)-594-9700 (Fax) (603)-594-0092 |

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

VTI Intraoperative Doppler Systems

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

| | | |
|--|--|---|
| 11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) | 12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) David Regan (Title) Vice President - Sales | |
| ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 12 Murphy Drive Nashua, NH 03062 | 14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) (603)-594-9700 (Fax) (603)-594-0092 | 15. DATE OF CERTIFICATION 07/02/2008 |

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.
9. **Certification** - This section contains three different check-off boxes.
Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
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 number.

Records Processed under FOIA Request # 2015-3943, Released by CDRH on 9-10-2015
SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K082870

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) K860651/A1, K031091
2. Submitter's statement that both the **indication and the intended use** of the modified device as described in its labeling **has not changed** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device modifications, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the Fundamental Scientific Technology of the modified device **has not changed**.

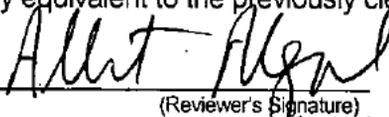
This change was for: use of (b) (4)
operate from an external AC-to-DC power converter, and (b) (7)

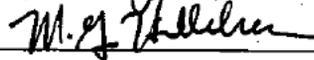
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and **structure of device. Other than the three changes described above, the devices are the same as the predicate devices.**
5. **A Design Control Activities Summary** which includes (all present):
 - a) Identification of Risk Analysis methods 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 verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

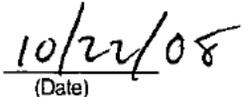
6. **A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices) (all present).**

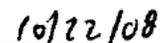
The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Comments


(Reviewer's Signature)




(Date)



revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

| | Yes | No | |
|--|-----|----|-------------------------------------|
| 1. Same Indication Statement? | X | | If YES = Go To 3 |
| 2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | X | If YES = Stop NSE |
| 3. Same Technological Characteristics? | X | | If YES = Go To 5 |
| 4. Could The New Characteristics Affect Safety Or Effectiveness? | | | If YES = Go To 6 |
| 5. Descriptive Characteristics Precise Enough? | X | | If NO = Go To 8 If YES = Stop SE |
| 6. New Types Of Safety Or Effectiveness Questions? | | | If YES = Stop NSE |
| 7. Accepted Scientific Methods Exist? | | | If NO = Stop NSE |
| 8. Performance Data Available? | | | If NO = Request Data |
| 9. Data Demonstrate Equivalence? | | | Final Decision: SE |

MEMORANDUM

From: Albert E. Moyal, Engr. Date: 10/21/08
CDRH/ODE/DCD/CSPB
To: Record
Re: K082870
Device: VTI Intraoperative Doppler System
Firm: Vascular Technology Inc.

Subject: Email and Telephone Contacts with Sponsor

Contact with Sponsor

- Monday October 6, 2008: I emailed the sponsor requesting clarification information on the changes.

(b) (4) Please explain the reason(s) that (b) (4)

- o Please elaborate on the use of the A/C to DC power converter and the reason for adding it as an alternate power source.
- o Please clarify on what exactly is the additional (b) (4) that is being added to the four device models.

- Monday October 6, 2008: The sponsor emailed the responses to the questions above:

Thank you for your email. Below you will find my response to your questions. I will call you to make sure I have fully answered your questions.

- Please explain the reason(s) that (b) (4)

(b) (4) Response: Utilizing a (b) (4) reduces the risk of failure from a moderate to minor risk, if the device is (b) (4). The Doppler transceiver is a portable, lightweight device and with the addition of a power cord, there was some concern that the cord could become (b) (4)

(b) (4)

FDA Response: This response and the reasons given are satisfactory.

- Please elaborate on the use of the A/C to DC power converter and the reason for adding it as an alternate power source.

Response: The current cleared devices use 8 AA alkaline batteries as a power source. Users have requested the addition of A/C power to eliminate the need to locate 8 fresh batteries and change them out in the OR.

(b) (4)

- Please clarify on what exactly is the additional (b) (4) that is being added to the four device models.

FDA Response: This response is satisfactory.

Response: In addition to using (b) (4)

(b) (4)

FDA Response: This clarification is satisfactory.

- October 10, 2008: Telephone contact w/sponsor. Requested diagram of circuitry regarding isolation incorporated.
- October 10, 2008: Email received from sponsor with diagram. See attached.

Moyal, Albert E.

From: David Regan (VTI) [dregan@vti-online.com]
Sent: Wednesday, October 08, 2008 9:41 PM
To: Moyal, Albert E.
Subject: RE: K082870 - VTI Intraoperative Doppler System

Hello Albert,

Thank you for your email. Below you will find my response to your questions. I will call you to make sure I have fully answered your questions.

(b) (4) Please explain the reason(s) that (b) (4)

(b) (4)

Utilizing a (b) (4) reduces the risk of failure from a moderate to minor risk, if the device is (b) (4). The Doppler transceiver is a portable, lightweight device and with the addition of a power cord, there was some concern that the cord could become

(b) (4)

- Please elaborate on the use of the A/C to DC power converter and the reason for adding it as an alternate power source.

The current cleared devices use 8 AA alkaline batteries as a power source. Users have requested the addition of A/C power to eliminate the need to locate 8 fresh batteries and change them out in the OR.

- Please clarify on what exactly is the additional (b) (4) that is being added to the four device models. (b) (4)

In addition to using (b) (4)

(b) (4)

Please let me know if you need additional information.

David L. Regan

Vice President --Sales

Vascular Technology

Hearing is Believing

T: 603-594-9700 (ex. 22)

T: 800-550-0856

C: 603-508-1211

F: 603-594-0092

NOTICE: This electronic message, including all attachments, is intended solely for the use of the individuals or entity named above, and may contain CONFIDENTIAL, PRIVILEGED and/or TRADE SECRET INFORMATION. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution or copying of this electronic message, including any attachments, is strictly prohibited. If you receive this electronic message in error, please notify us immediately by telephone.

From: Moyal, Albert E. [mailto:albert.moyal@fda.hhs.gov]
Sent: Monday, October 06, 2008 3:20 PM
To: dregan@vti-online.com
Subject: K082870 - VTI Intraoperative Doppler System

Hi David,

My name is Albert Moyal and I am the reviewer for this 510(k) submission. I have looked over the file and I have a couple of quick questions regarding the devices and the changes being incorporated into them. They are as follows:

(b) (4) Please explain the reason(s) that (b) (4)

- Please elaborate on the use of the A/C to DC power converter and the reason for adding it as an alternate power source.
- Please clarify on what exactly is the additional (b) (4) device models.

Please do not hesitate to contact me if you have any questions.

Best regards,
Albert

Albert E. Moyal, Engr.
Biomedical/Electrical Engineer
Circulatory Support and Prosthetic Devices
Division of Cardiovascular Devices
Phone: (240) 276-4198
Fax: (240) 276-4166

Moyal, Albert E.

From: David Regan (VTI) [dregan@vti-online.com]
Sent: Friday, October 10, 2008 11:58 AM
To: Moyal, Albert E.
Subject: RE: K082870 - VTI Intraoperative Doppler System
Attachments: 200124-15 00 1.pdf

Hello Albert,

It was my pleasure speaking with a fellow Red Sox fan today. Engineering was able to provide me with a PDF of (b) (4) please let me know if you require any additional information.

David L. Regan

Vice President –Sales

Vascular Technology

Hearing is Believing

T: 603-594-9700 (ex. 22)

T: 800-550-0856

C: 603-508-1211

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David

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Sent: Monday, October 06, 2008 3:20 PM
To: dregan@vti-online.com
Subject: K082870 - VTI Intraoperative Doppler System

Hi David,

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(b) (4)

(b) (4) explain the reason(s) that

- Please elaborate on the use of the A/C to DC power converter and the reason for adding it as an alternate power source.
- Please clarify on what exactly is the additional (b) (4) that is being added to the four device models.

Please do not hesitate to contact me if you have any questions.

Best regards,
Albert

Albert E. Moyal, Engr.
Biomedical/Electrical Engineer
Circulatory Support and Prosthetic Devices
Division of Cardiovascular Devices
Phone: (240) 276-4198
Fax: (240) 276-4166



COVER SHEET MEMORANDUM

From: Reviewer Name Albert Moyal

Subject: 510(k) Number K082870

To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

| Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.): | | YES | NO |
|---|--------------------------------------|-----|----|
| Indications for Use Page | Attach IFU | X | |
| 510(k) Summary / 510(k) Statement | Attach Summary | X | |
| Truthful and Accurate Statement | Must be present for a Final Decision | X | |
| Is the device Class III? | | | |
| If yes, does firm include Class III Summary? | Must be present for a Final Decision | | X |
| Does firm reference standards? (If yes, please attach form from http://www.fda.gov/oc/pacom/morechoices/fdaforms/FDA-3654.pdf) | | X | |
| Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC) | | | X |
| Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html) | | | X |
| Is this device intended for pediatric use only? | | | X |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) | | X | X |
| Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of Clinical Trials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.) | | X | X |
| Does this device include an Animal Tissue Source? | | | X |
| All Pediatric Patients age <= 21 | | | X |
| Neonate/Newborn (Birth to 28 days) | | | X |
| Infant (29 days - < 2 years old) | | | X |
| Child (2 years - < 12 years old) | | | X |
| Adolescent (12 years - < 18 years old) | | | X |
| Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age > 21 (different device design or testing, different protocol procedures, etc.) | | | X |
| Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old) | | | X |
| Nanotechnology | | | X |

| | | |
|--|--------------|-------------------------------------|
| Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html) | Contact OSB. | <input checked="" type="checkbox"/> |
| Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) | Contact OC. | <input checked="" type="checkbox"/> |

Regulation Number: 21CFR 870.2100 Class: CL II Product Code: DPW
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: M. J. Wilhelms CSPS 10/22/08
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 10/22/08
 (Division Director) (Date)