

510(k) Summary

JUL 20 2009

510(k) Sponsor: DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CA 91355

Device Name: PVAS™ Ported Vascular Access System

510(k) Contact: Jennifer Hessel, Director RA/QA
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

Summary Date: June 10, 2009

Trade Name: DermaPort Ported Vascular Access System (PVAS™)

Common Name: Hemodialysis Catheter, Implanted

Classification Name: 21 CFR 876.5540 Blood Access Device and Accessories, Class III,
Product Code: MSD

Predicate Device:
510(k) Number: K071202
Manufacture: DermaPort
Trade Name: Percutaneous Vascular Access System (PVAS)

1.0 Description of Device

The Ported Vascular Access System (PVAS™) has been developed to support central vascular access for hemodialysis and apheresis. This application is for the addition of a 15.5F catheter to the PVAS system and a dilating lead-in to replace the sheath during insertion.

The PVAS port consists of a percutaneous tubular conduit, through which a standard 14.5F or 15.5F polyurethane hemodialysis catheter enters the subcutaneous tunnel. An integral seal surrounds the catheter and prevents microbial migration along the catheter. The PVAS port is enclosed by a silicone anchor that braces the assembly to the skin, and an associated brake holds the catheter in place within the port. A tissue integrating biomaterial surrounds the port, providing anatomical fixation and prevention of microbial migration in a manner analogous to the Dacron cuff of a tunneled catheter.

1.1 Clinical Application

The clinical application of the DermaPort Ported Vascular Access System and catheter is consistent with clinical applications of the predicate DermaPort Percutaneous Vascular Access System cleared to market by 510(k) K071202.

2.0 Intended Use of Device

The indication for use of the PVAS is consistent with the classification of 21 CFR 876.5540 Blood Access Device and Accessories. The indication for use is:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

3.0 Technological Characteristics

The technical characteristics of the Ported Vascular Access System (PVAS™) are the same as the predicate devices in terms of intended use, insertion method, design, materials, performance, labeling, manufacturing process, and method of sterilization. The modifications include: addition of 15.5F catheters incorporation of dilating lead-in, removal of the sheath, replacement of non-valved dilator with a valved dilator, addition of suture to the kit, and replacement of polycarbonate injection caps with ABS injection caps

4.0 Data Summary

The design differences were tested to verify the removal of the sheath, addition of dilating lead-in, change in mesh geometry, 15.5 F catheter and new or modified accessories did not impact the function, performance or safety of the device. The performance testing performed to verify these changes consisted of insertion testing, histopathological analysis of the mesh following implantation in a chronic animal model, biomechanical testing of tissue ingrowth, mesh to port removal force for modified geometry, catheter/port retention testing, microbial ingress and flow versus pressure for new catheter sizes and functional/biocompatibility testing for new accessories. The test methods used to evaluate these changes were equivalent to those applied to the predicate device.

5.0 Conclusions

The modifications to the DermaPort PVAS were evaluated as required by the risk analysis and Design Control requirements. The modified PVAS does not raise new questions of safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2009

Ms. Jennifer Hessel
Director, Regulatory Affairs and Quality Assurance
DermaPort, Inc.
25102 Rye Canyon Loop, Suite 110
SANTA CLARITA CA 91355

Re: K091760

Trade/Device Name: DermaPort Ported Vascular Access System (PVAS)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: July 13, 2009
Received: July 15, 2009

Dear Ms. Hessel:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

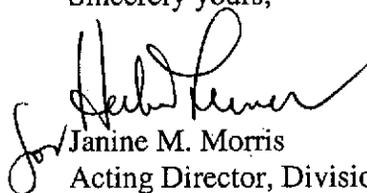
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (301) 796-5484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 301-796-6045. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K091760

Device Name: DermaPort Ported Vascular Access System (PVAS)

Indications for Use:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

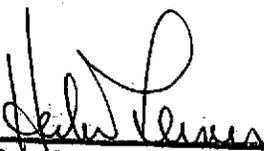
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091760



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2009

Ms. Jennifer Hessel
Director, Regulatory Affairs and Quality Assurance
DermaPort, Inc.
25102 Rye Canyon Loop, Suite 110
SANTA CLARITA CA 91355

Re: K091760

Trade/Device Name: DermaPort Ported Vascular Access System (PVAS)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: July 13, 2009
Received: July 15, 2009

Dear Ms. Hessel:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

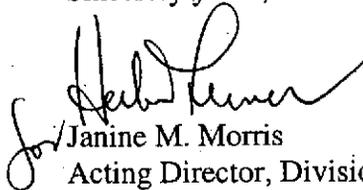
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Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K091760

Device Name: DermaPort Ported Vascular Access System (PVAS)

Indications for Use:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

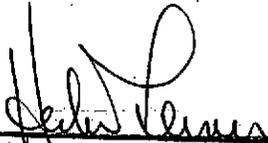
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091760



July 14, 2009

DERMAPORT, INC
25102 RYE CANYON LOOP SUITE 110
SANTA CLARITA, CALIFORNIA 91355
UNITED STATES
ATTN: JENNIFER HESSEL

510k Number: K091760

Product: DERMAPORT PORTED VASCULAR ACCE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k 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



June 16, 2009

DERMAPORT, INC
25102 RYE CANYON LOOP SUITE 110
SANTA CLARITA, CALIFORNIA 91355
UNITED STATES
ATTN: JENNIFER HESSEL

510k Number: K091760

Received: 6/16/2009

Product: DERMAPORT PORTED VASCULAR
+ GGS

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

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.

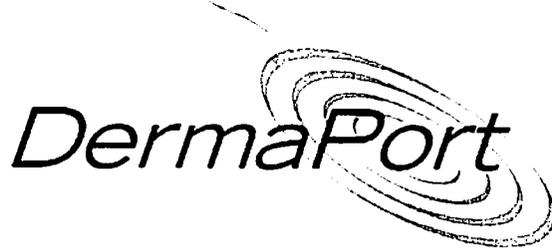
Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. 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/electsub.html. In addition, the 510(k) Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv.

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



DermaPort

K091760

June 10, 2009

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

FDA CDRH DMC
JUN-16 2009
Received

Re: Special 510(k), Modification of the PVAS

The enclosed Special 510(k) Pre-Market Notification is submitted in compliance with 21 CFR 807. This Special 510(k) Pre-Market Notification supports commercial introduction of a modification to the PVAS, cleared to market by 510(k) K071202. Enclosed are one paper and one electronic copy of the submission. The electronic copy provided, per the FDA web instructions, is an exact duplicate of the paper submission.

This modification meets the qualifications for a Special 510(k) premarket notification submission as defined in the FDA Guidance "The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", March, 1998. The following summarizes the rationale for submitting a Special 510(k):

1. The modified PVAS is a modification of the existing DermaPort PVAS.
2. The intended use of the modified PVAS is the same as the unmodified PVAS.
3. This modification does not affect the fundamental scientific technological basis of the PVAS.
4. All changes were made in compliance with the DermaPort Design Control process and changes are complete.

The risks of this modification were evaluated. The Risk Analysis is provided in Section 5.0 of this premarket notification. The modification is appropriate for evaluation by Design Control conformance.

The following information is provided for reference.

1. 510(k) Sponsor: DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CA 91355

K20

2. 510(k) Contact: Jennifer Hessel, Director Regulatory Affairs and Quality Assurance.
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

3. Trade Name: DermaPort Ported Vascular Access System (PVAS™)

4. Common Name: Hemodialysis Catheter, Implanted

5. Manufacturing Site Address:

These devices are manufactured by DermaPort, Inc. at:
DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CA 91355
DermaPort, Inc. FDA Establishment Registration Number: 3006234629

The following contract manufacturer will perform supporting manufacturing operations:

(b) (4)

Contract sterilization is performed by:

(b) (4)

6. Classification Name: Predicate PVAS device has been found substantially equivalent to 21 CFR 876.5540 Blood Access Device and Accessories, Class III, Product Code: MSD.

7. Reviewing Branch: Gastroenterology and Renal Devices Branch

8. Reason for 510(k): Modification to existing device.

9. Predicate/Unmodified Device:

510(k) Number: K071202

Trade Name: Percutaneous Vascular Access System (PVAS)

10. Compliance to Special Controls: standards that only apply to the change

Compliance to Standards: The following Recognized Consensus Standards are applicable and were applied to the device under review:

ANSI/AAMI/ISO 11135:2007 Medical devices - Validation and routine control of ethylene oxide sterilization

ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System



ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System

ASTM F756:2000, Standard Practice for Assessment of Hemolytic Properties of Materials

ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements: Luer connections

ISO 10555-1:1995 Sterile, Single-use Intravascular Catheters – Part 1: General Requirements

ISO 10555-3:1996 Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters

ISO 10993-1:2000 Biological evaluation of medical devices-Part 1: Evaluation and Testing

ISO 10993-5:1999 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity

ISO 10993-7: 2008 Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals

ISO 10993-10:2002 Biological evaluation of medical devices-Part 10: Tests for Irritation and Sensitization

ISO 10993-11:1993 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity

Compliance to DermaPort Design Control Procedures

Please contact me with any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jennifer Hessel". The signature is fluid and cursive, with a large initial "J" and "H".

Jennifer Hessel
Director Regulatory Affairs/Quality Assurance
DermaPort, Inc.
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

Enclosure

Modified PVAS

Ported Vascular Access System

Special 510(k) Pre-Market Notification

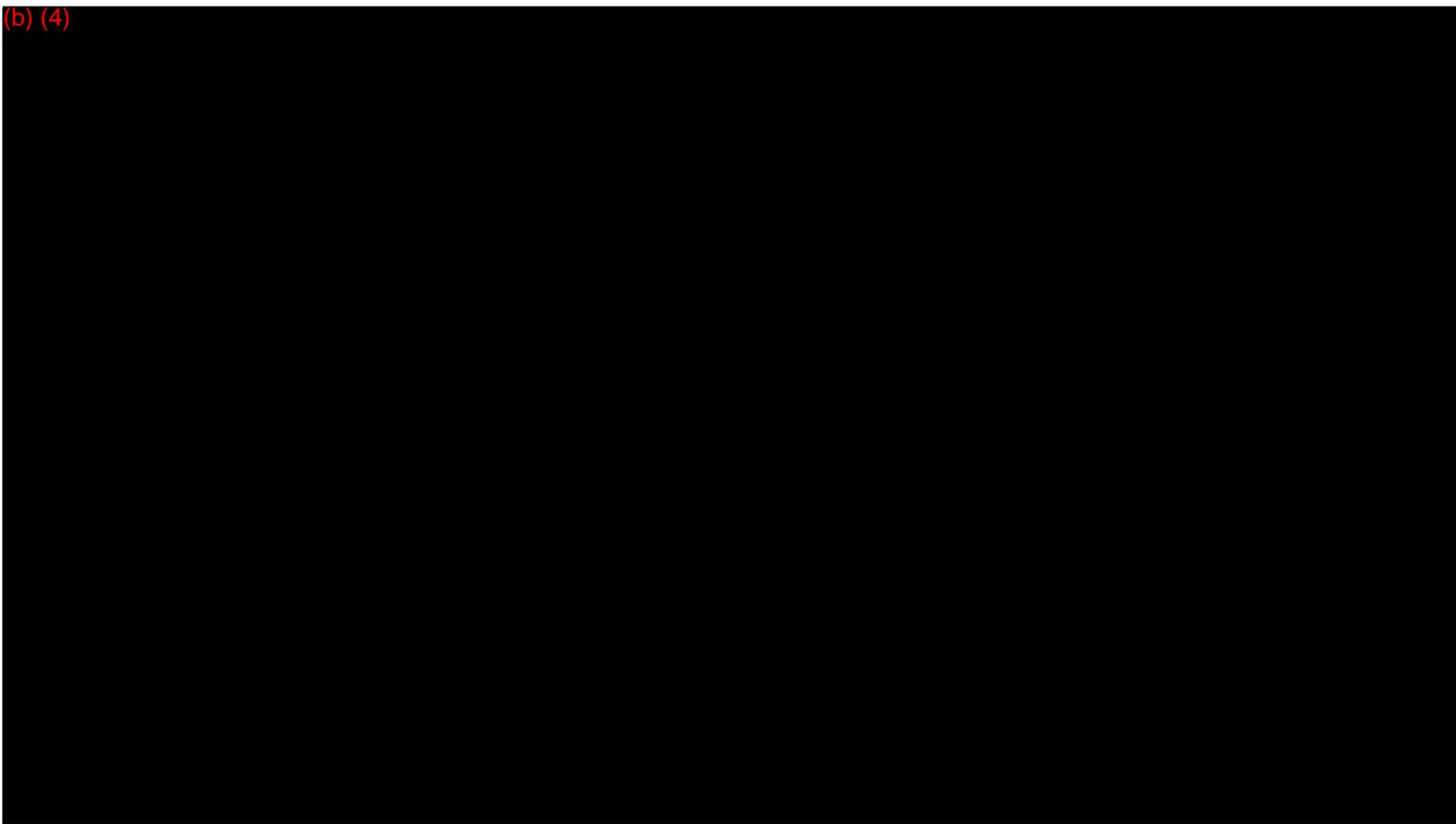
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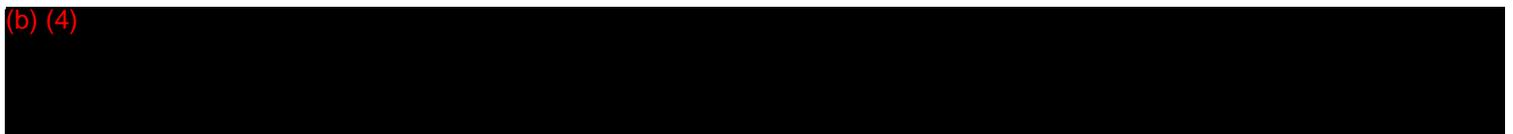
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER (b) (4) Write the Payment Identification number		
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html				
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) DERMAPORT INC 25102 RYE CANYON LOOP SUITE 110 Santa Clara CA 91355 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 201986561	2. CONTACT NAME Jennifer Hessel 2.1 E-MAIL ADDRESS jhessel@dermaport.com 2.2 TELEPHONE NUMBER (include Area code) 661-3627904 2.3 FACSIMILE (FAX) NUMBER (Include Area code)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <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 </td> <td style="vertical-align: top;"> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>			<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD098330				
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)				
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="vertical-align: top;"> <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 </td> </tr> </table>			<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				
(b) (4) AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION		10-Jun-2009		

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

(b) (4)



(b) (4)



CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
 OMB No. 0910-0120
 Expiration Date: August 31, 2010.
 See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number <i>(if known)</i>
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SECTION A TYPE OF SUBMISSION

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

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 DermaPort, Inc.	Establishment Registration Number <i>(if known)</i> 3006234629		
Division Name <i>(if applicable)</i>	Phone Number <i>(including area code)</i> 661-362-7904		
Street Address 25102 Rye Canyon Loop, Suite 110	FAX Number <i>(including area code)</i> 661-362-7902		
City Santa Clarita	State / Province CA	ZIP/Postal Code 91355	Country USA
Contact Name Jennifer Hessel			
Contact Title Director Regulatory Affairs / Quality Assurance	Contact E-mail Address jhessel@dermaport.com		

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

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

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <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"/> Packaging <input type="checkbox"/> Sterilization <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 Characteristics <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"/> Response 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>): The submission is for a design modification that does not impact the indications for use or results in a change in technology. This application is for the addition of a 15.5F catheter to the PVAS system , a dilating lead-in to replace the sheath during insertion and modifications to the accessories.		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

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

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K071202	1 Percutaneous Vascular Access System (PVAS)	1 DermaPort
2		2	2
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Hemodialysis Catheter, Implanted

	Trade or Proprietary or Model Name for This Device	Model Number
1	DermaPort Ported Vascular Access System (PVAS™)	1
2		2
3		3
4		4
5		5

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

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

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code MSD	C.F.R. Section (if applicable) 21 CFR 876.5540	Device Class <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input checked="" type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Gastroenterology - Urology		

Indications (from labeling)
 The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and the catheter is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

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

FDA Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number 3006234629	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
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Company / Institution Name DermaPort, Inc.	Establishment Registration Number 3006234629
---	---

Division Name (if applicable)	Phone Number (including area code) 661-362-7900
-------------------------------	--

Street Address 25102 Rye Canyon Loop, Suite 110	FAX Number (including area code) 661-362-7902
--	--

City Santa Clarita	State / Province CA	ZIP Code 91355	Country USA
-----------------------	------------------------	-------------------	----------------

Contact Name	Contact Title	Contact E-mail Address
--------------	---------------	------------------------

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number (b)(4)	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
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Company / Institution Name (b)(4)	Establishment Registration Number
--------------------------------------	-----------------------------------

Division Name (if applicable)	Phone Number (including area code)
-------------------------------	------------------------------------

Street Address (b)(4)	FAX Number (including area code)
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City (b)(4)	State / Province	ZIP Code	Country
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Contact Name	Contact Title	Contact E-mail Address
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<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
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Company / Institution Name (b)(4)	Establishment Registration Number
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Division Name (if applicable)	Phone Number (including area code)
-------------------------------	------------------------------------

Street Address (b)(4)	FAX Number (including area code)
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City (b)(4)	State / Province	ZIP Code	Country
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Contact Name	Contact Title	Contact E-mail Address
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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	ANSI/AAMI/ISO 11135	ANSI/AAMI/ISO	ANSI/AAMI/ISO 11135:2007 Medical devices - Validation and routine control of ethylene oxide sterilization	2007	05/01/2007
2	ASTM F756	ASTM	ASTM F756:2000, Standard Practice for Assessment of Hemolytic Properties of Materials	2000	07/10/2000
3	ISO 594-1	ISO	ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements: Luer connections	1986	6/15/1986
4	ISO 10555-1	ISO	ISO 10555-1:1995 Sterile, Single-use Intravascular Catheters – Part 1: General Requirements	1995	6/15/1995
5	ISO 10555-3	ISO	ISO 10555-3:1996 Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters	1996	6/15/1996
6	ISO 10993-1	ISO	ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and Testing	2003	8/1/2003
7	ISO 10993-5	ISO	ISO 10993-5:1999 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity	1999	5/1/1999

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:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

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.

8	Standards No. ISO 10993-7	Standards Organization ISO	Standards Title ISO 10993-7: 2008 Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals	Version 2008	Date 10/15/2008
9	Standards No. ISO 10993-10	Standards Organization ISO	Standards Title ISO 10993-10:2002 Biological evaluation of medical devices-Part 10: Tests for Irritation and Sensitization	Version 2002	Date 9/1/2002
10	Standards No. ISO 10993-11	Standards Organization ISO	Standards Title ISO 10993-11:2006 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity	Version 1993	Date 11/2/2006
11	Standards No. ASTM D4169	Standards Organization ASTM	Standards Title ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System	Version 2005	Date 10/1/2005
9	Standards No.	Standards Organization	Standards Title	Version	Date
9	Standards No.	Standards Organization	Standards Title	Version	Date

Special 510(k) Pre-Market Notification Elements List

510(k) Element	510(k) Submission Location
Cover letter	Cover Letter
Table of Contents	Table of Contents
Truthful and Accurate Statement	Section 2.0
Device's Trade Name, Device's Classification Name and Establishment Registration Number	Cover Letter: 3, 5, 6
Device Classification Regulation Number and Regulatory Status	Cover Letter: 6
Proposed Labeling	Section 3.0
Statement of Indications for Use	Attachment E
Substantial Equivalence Comparison	Section 4.0
510(k) Summary or 510(k) Statement	Attachment D
Description of the device modification, diagrams, drawings, photographs. Identification of legally marketed predicate device.	Section 1.0
Compliance with performance standards	Section 6.0 and 7.0
Class III Certification and Summary	Attachment G
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study.	Not Applicable
510(k) Kit Certification	Not Applicable
Required Elements for a SPECIAL 510(k) submission	
Name and 510(k) number of the sponsor's own, unmodified predicate device.	Cover Letter: 9
A description of the modified device and a comparison to the sponsor's predicate device.	Sections 1.0 and 4.0
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.	Section 1.0
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	Section 1.0
A Design Control Activities Summary that includes the following elements: a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. c. A Declaration of Conformity with design controls that includes the following statements: A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	Section 5.0 Sections 5.0, 6.0 and 7.0 Section 6.0 and 7.0



June 10, 2009

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

Re: Special 510(k), Modification of the PVAS

The enclosed Special 510(k) Pre-Market Notification is submitted in compliance with 21 CFR 807. This Special 510(k) Pre-Market Notification supports commercial introduction of a modification to the PVAS, cleared to market by 510(k) K071202. Enclosed are one paper and one electronic copy of the submission. The electronic copy provided, per the FDA web instructions, is an exact duplicate of the paper submission.

This modification meets the qualifications for a Special 510(k) premarket notification submission as defined in the FDA Guidance "The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", March, 1998. The following summarizes the rationale for submitting a Special 510(k):

1. The modified PVAS is a modification of the existing DermaPort PVAS.
2. The intended use of the modified PVAS is the same as the unmodified PVAS.
3. This modification does not affect the fundamental scientific technological basis of the PVAS.
4. All changes were made in compliance with the DermaPort Design Control process and changes are complete.

The risks of this modification were evaluated. The Risk Analysis is provided in Section 5.0 of this premarket notification. The modification is appropriate for evaluation by Design Control conformance.

The following information is provided for reference.

1. 510(k) Sponsor: DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CA 91355

2. 510(k) Contact: Jennifer Hessel, Director Regulatory Affairs and Quality Assurance.
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

3. Trade Name: DermaPort Ported Vascular Access System (PVAS™)

4. Common Name: Hemodialysis Catheter, Implanted

5. Manufacturing Site Address:

These devices are manufactured by DermaPort, Inc. at:
DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CA 91355
DermaPort, Inc. FDA Establishment Registration Number: 3006234629

The following contract manufacturer will perform supporting manufacturing operations:

(b) (4)

Contract sterilization is performed by:

(b) (4)

6. Classification Name: Predicate PVAS device has been found substantially equivalent to 21 CFR 876.5540 Blood Access Device and Accessories, Class III, Product Code: MSD.

7. Reviewing Branch: Gastroenterology and Renal Devices Branch

8. Reason for 510(k): Modification to existing device.

9. Predicate/Unmodified Device:

510(k) Number: K071202

Trade Name: Percutaneous Vascular Access System (PVAS)

10. Compliance to Special Controls: standards that only apply to the change
Compliance to Standards: The following Recognized Consensus Standards are applicable and were applied to the device under review:

ANSI/AAMI/ISO 11135:2007 Medical devices - Validation and routine control of ethylene oxide sterilization

ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System

ASTM F756:2000, Standard Practice for Assessment of Hemolytic Properties of Materials

ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements: Luer connections

ISO 10555-1:1995 Sterile, Single-use Intravascular Catheters – Part 1: General Requirements

ISO 10555-3:1996 Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters

ISO 10993-1:2000 Biological evaluation of medical devices-Part 1: Evaluation and Testing

ISO 10993-5:1999 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity

ISO 10993-7: 2008 Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals

ISO 10993-10:2002 Biological evaluation of medical devices-Part 10: Tests for Irritation and Sensitization

ISO 10993-11:1993 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity

Compliance to DermaPort Design Control Procedures

Please contact me with any questions.

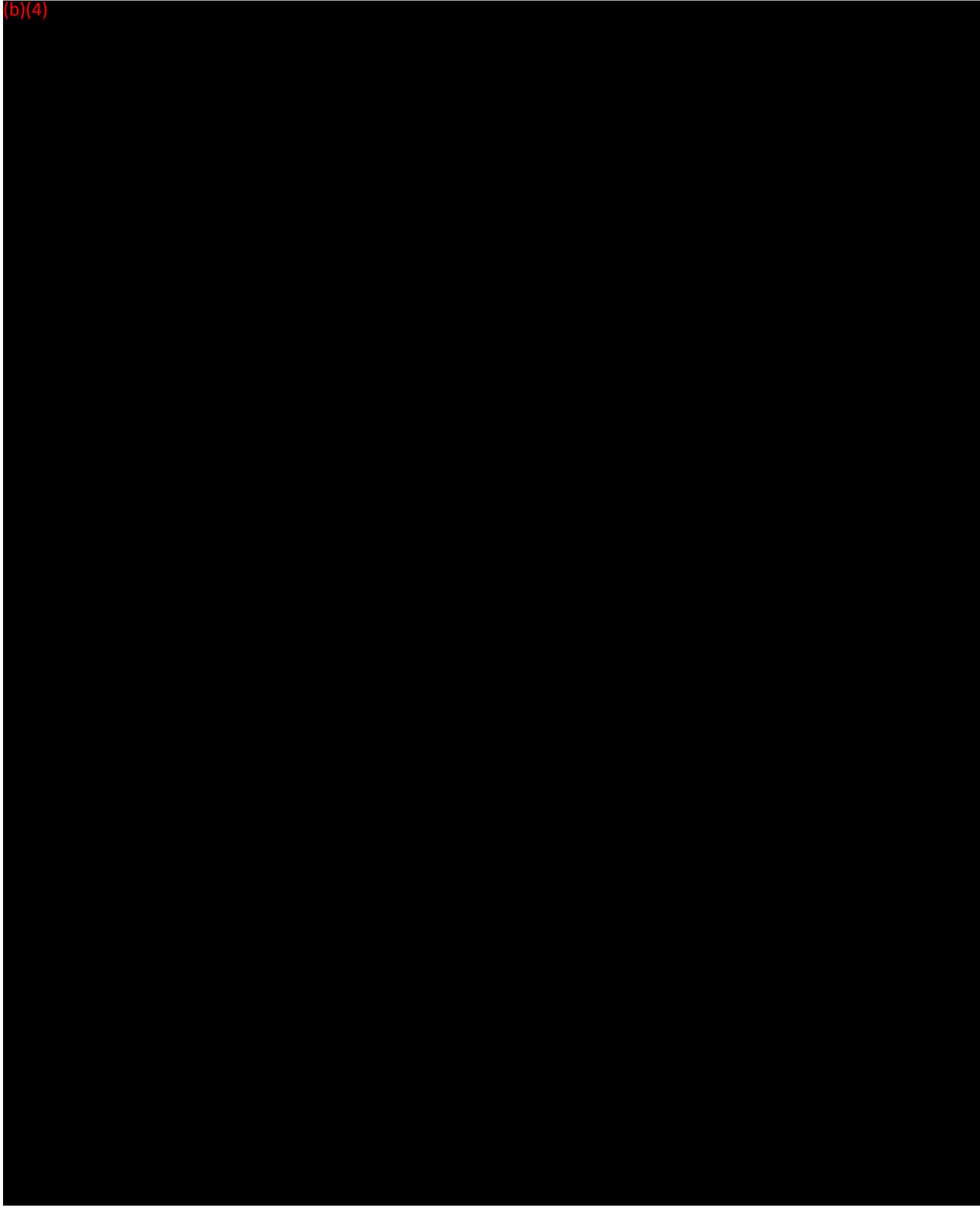
Sincerely,

Jennifer Hessel
Director Regulatory Affairs/Quality Assurance
DermaPort, Inc.
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

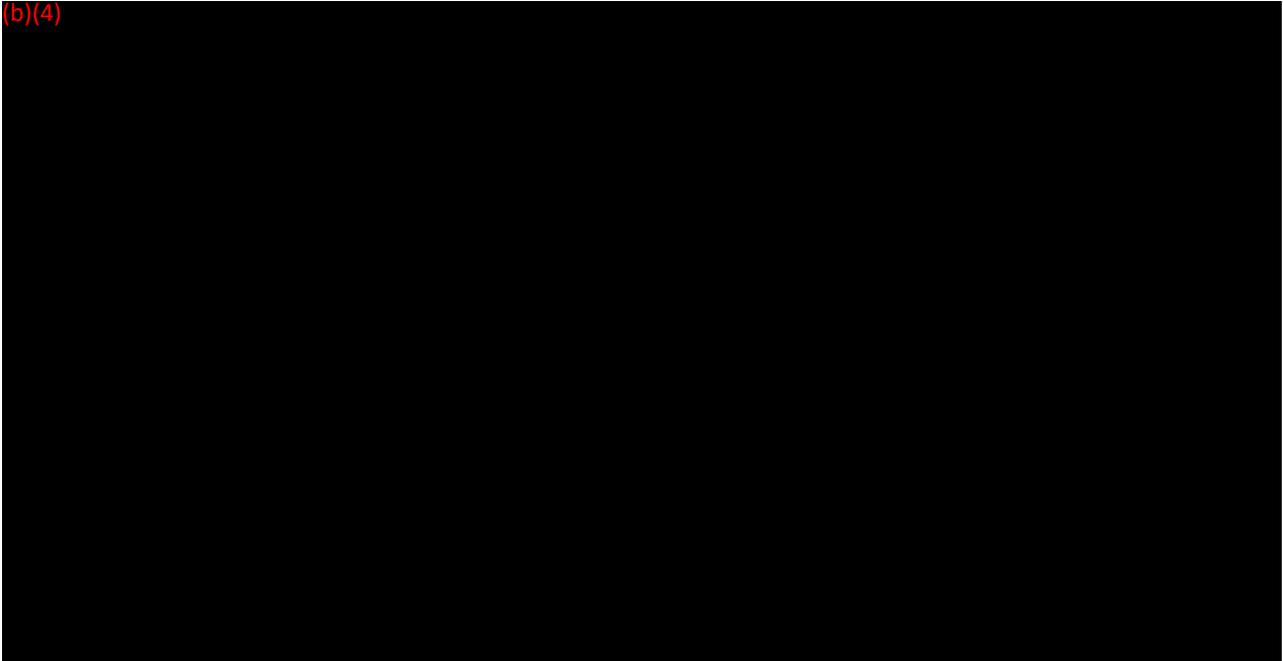
Enclosure

1.0 Description of Modified Device, Drawings, Photographs

(b)(4)

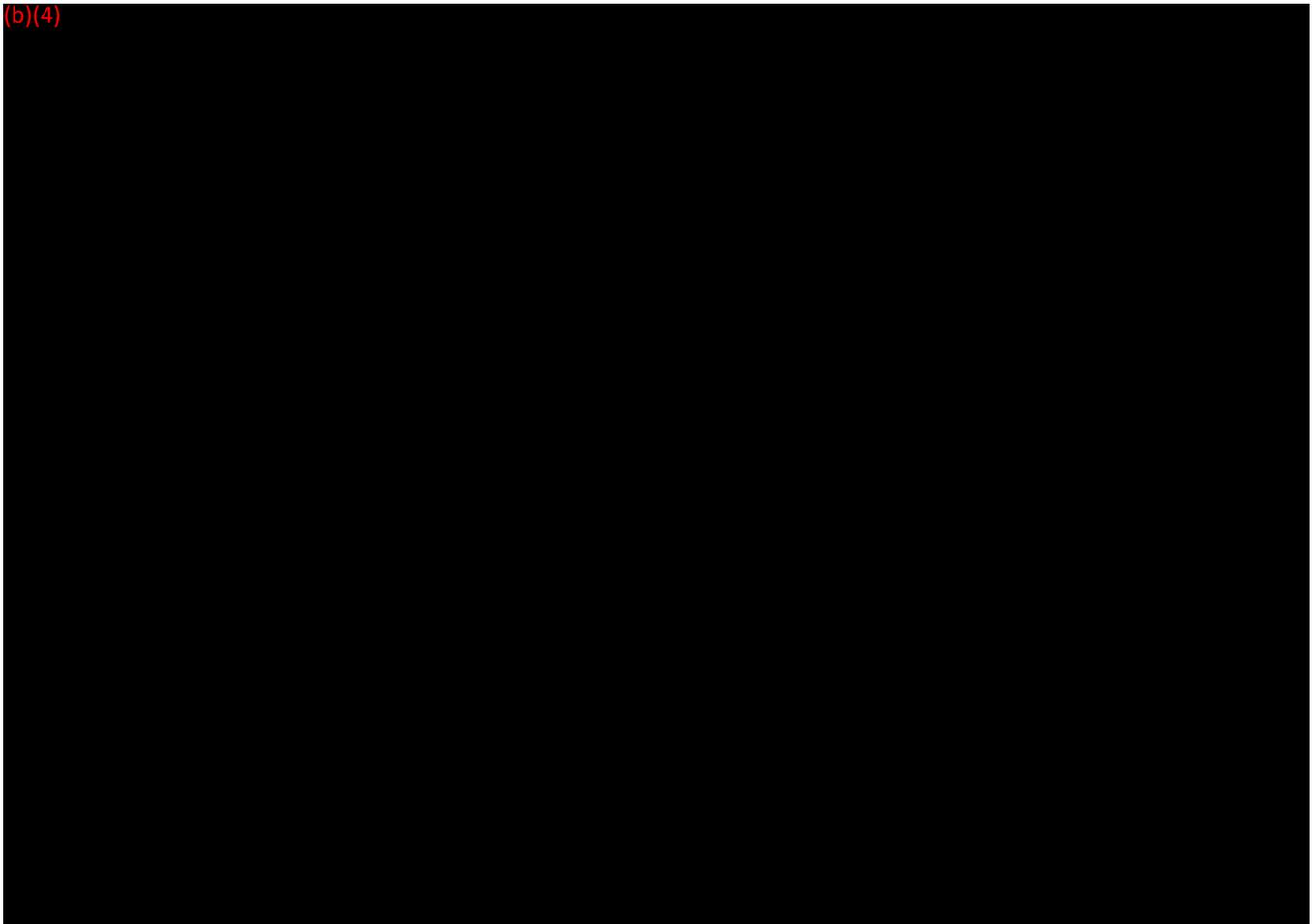


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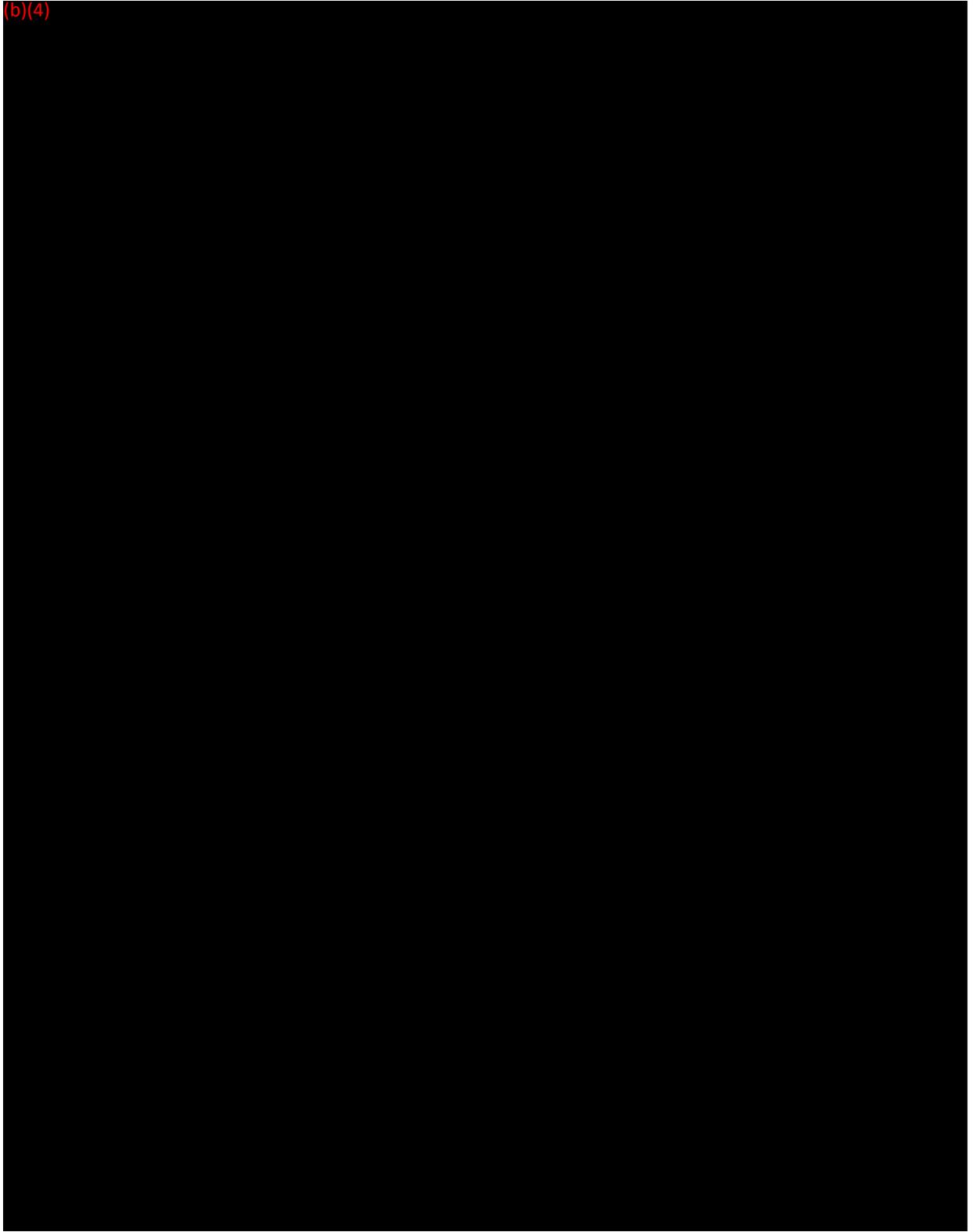


1.1 Summary of Modifications

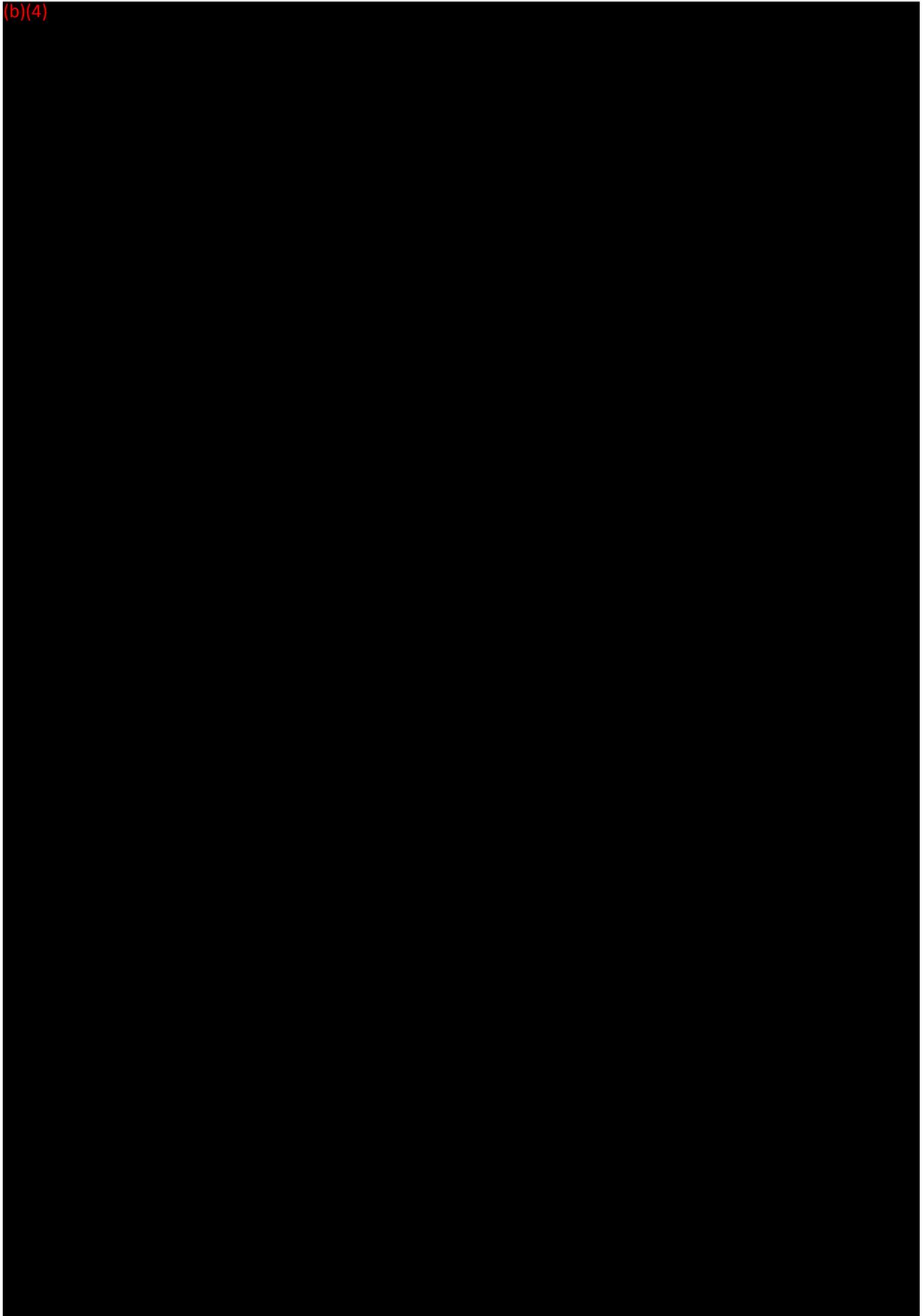
(b)(4)



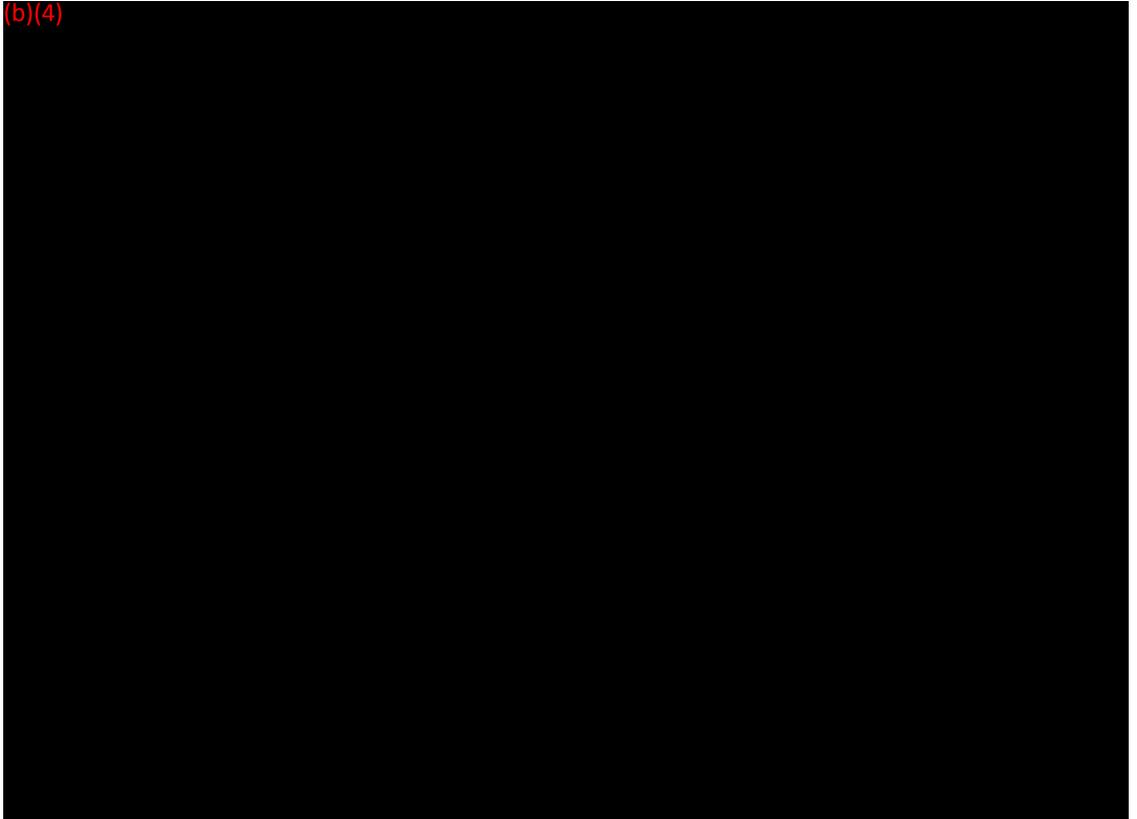
(b)(4)



(b)(4)

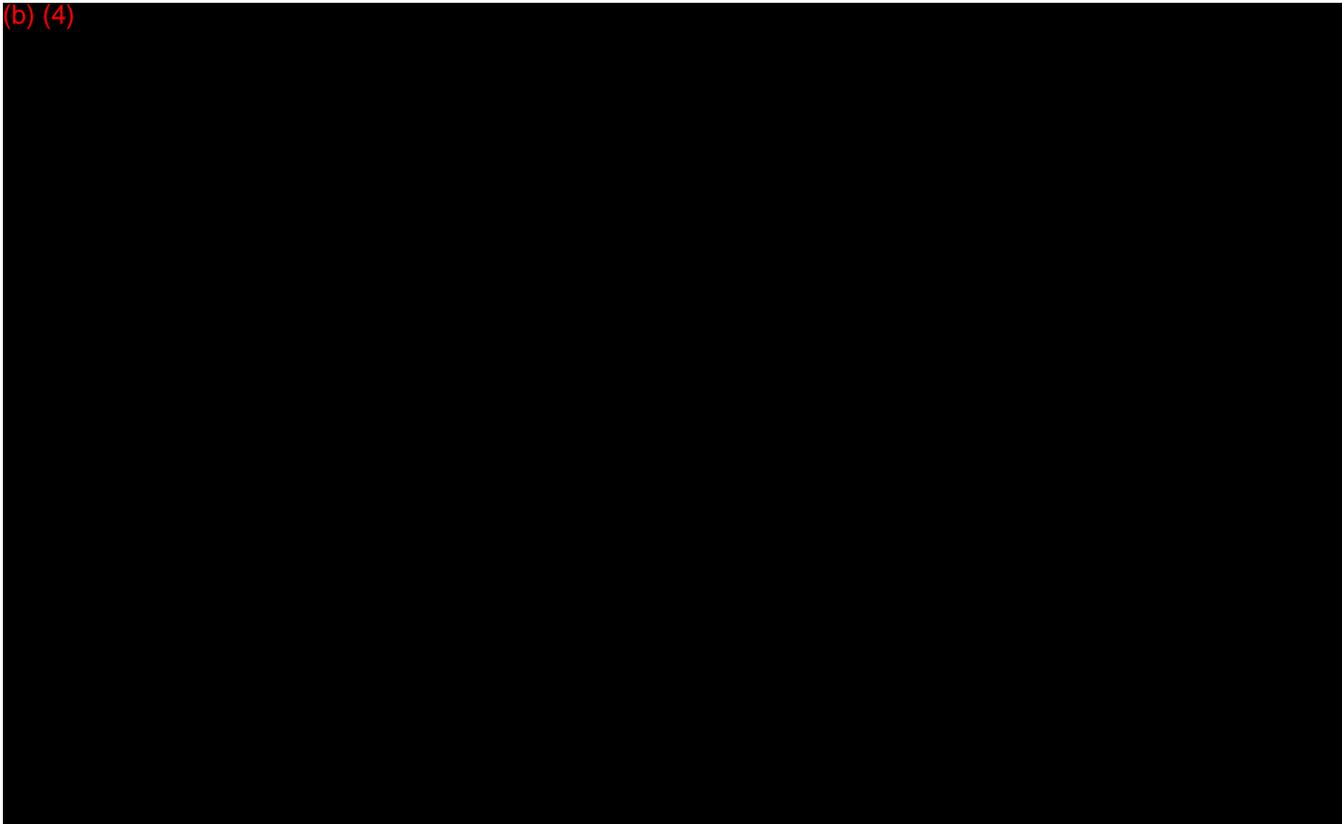


(b)(4)

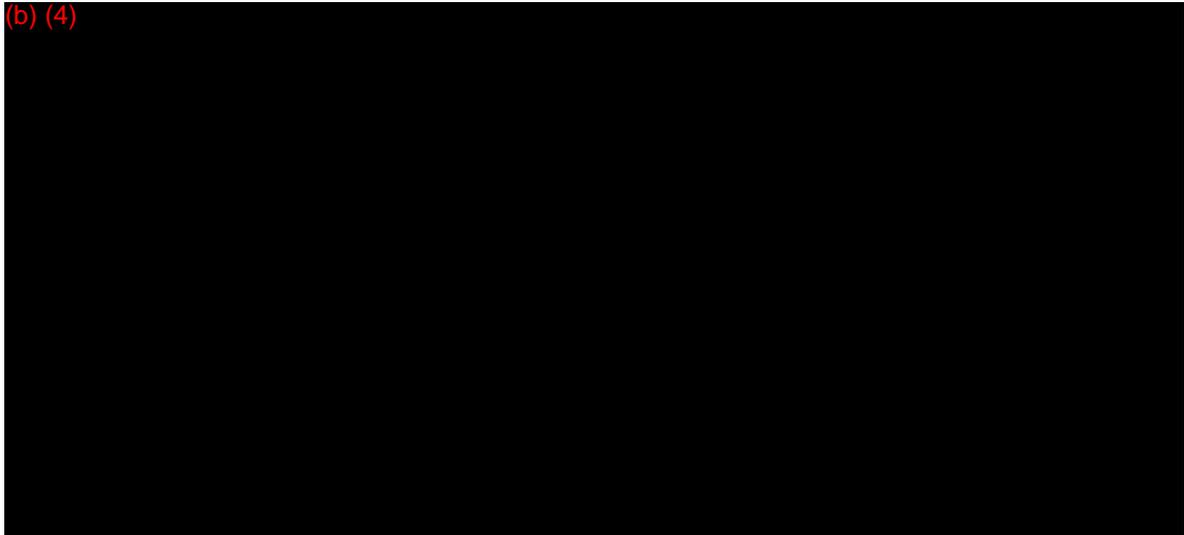


(6) Addition or changes to the following accessories in the PVAS kit have been made:

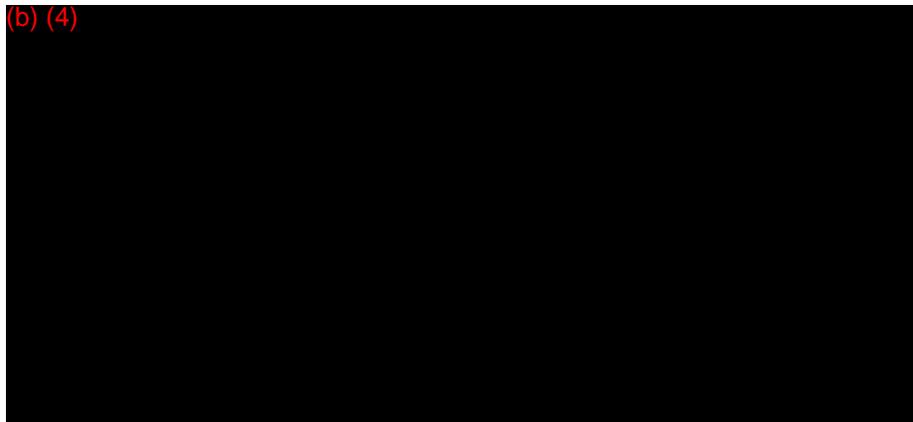
(b) (4)



(b) (4)



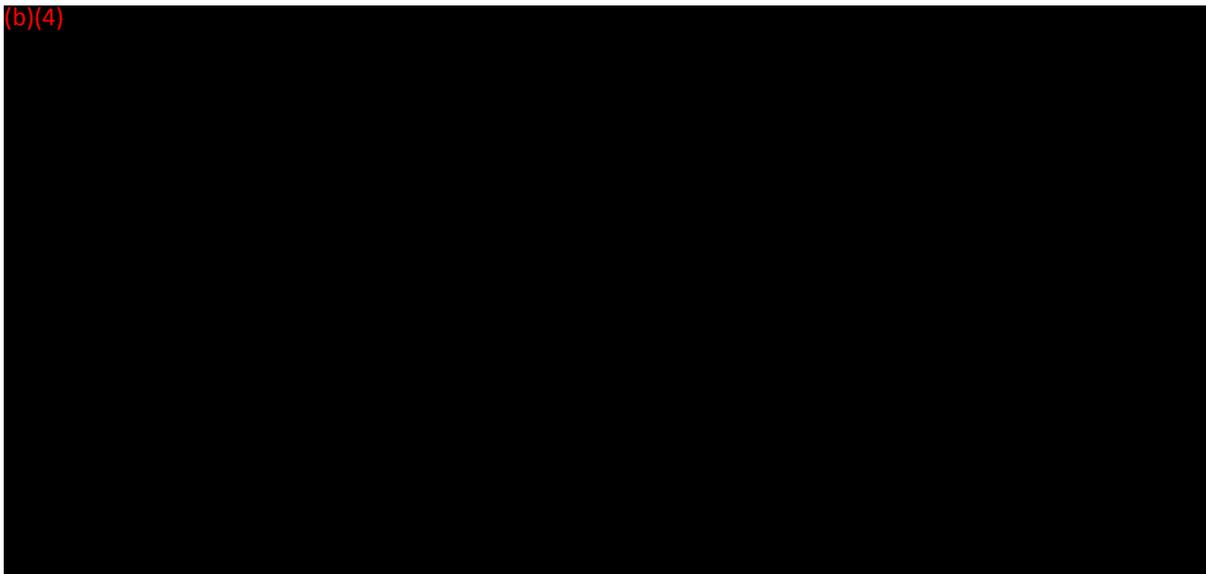
(b) (4)



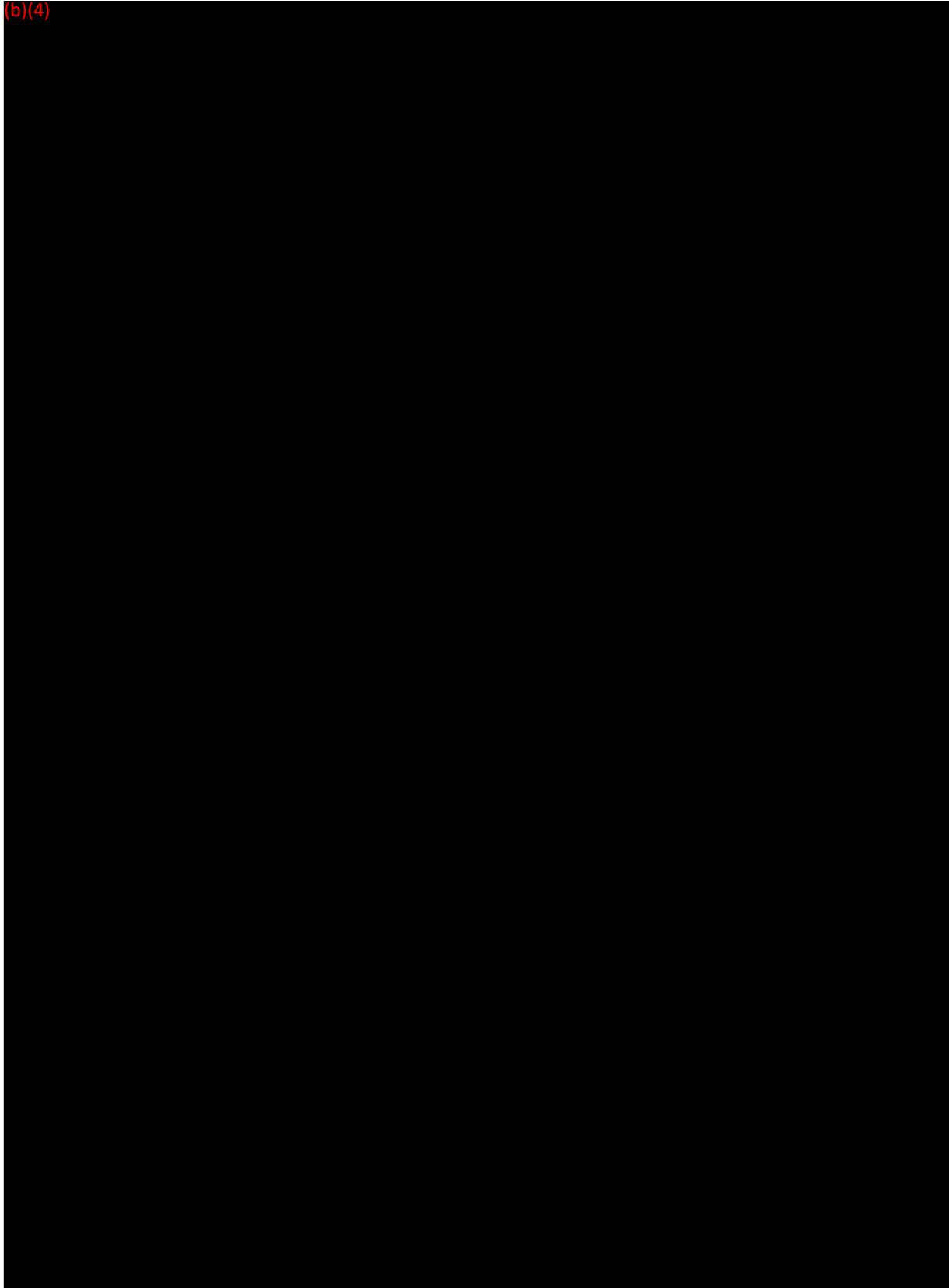
Picture 1.1-4: PVAS with tied polyester suture

The following non-significant changes were made to the PVAS since the original 510(k) submission and were controlled under the design control system:

(b)(4)



(b)(4)



(b) (4)



Picture 1.1-5: PVAS marked design change

- (7) Modification to Instructions for Use for clarification of suture use, the following changes were made:
- a. Deleted the directions in the Catheter Securement and Catheter Exchange sections, which instructed the user to suture the catheter hub to the skin and to remove the catheter hub sutures when exchanging or removing the catheter, respectively. This change was made in response to observations of clinical use, which demonstrated that suturing both the anchor and the catheter hub applied tension on the port with patient movement. The PVAS product had two sets of suture eyelets while standard cuffed catheters only have one. This change in the IFU text will clarify the suture procedure.
 - b. In addition, instructions were added to direct the user to remove the anchor sutures at 6 weeks, rather than to leave them in place for the life of the implant. Standard care discourages the use of permanent transcutaneous sutures. Six weeks is sufficient time for ingrowth into the PVAS mesh cuff, therefore the anchor sutures are no longer required after 6 week.

1.2 Clinical Application

The DermaPort Ported Vascular Access System (PVAS) was designed to facilitate hemodialysis catheter placement, repositioning, and exchange procedures while maintaining catheter attachment, bacterial barrier and fixation functions. The clinical application and intended use of the DermaPort Ported Vascular Access System and catheter remains unchanged from the predicate DermaPort Percutaneous Vascular Access System cleared to market by 510(k) K071202. The class III summary has been updated to include clinical experience with the product. Refer to Attachment G for the Class III summary

The PVAS port is an accessory to the implanted hemodialysis catheter, supporting percutaneous access to the central venous system for hemodialysis and apheresis. The PVAS port consists of a percutaneous tubular conduit, through which a standard 14.5F or 15.5F polyurethane hemodialysis catheter enters the subcutaneous tissue. An integral three (3) wiper seal surrounds the catheter and prevents microbial migration along the catheter. The port is enclosed by a silicone anchor that braces the assembly to the skin, and an associated brake holds the catheter in place within the port.

The tissue integrating (b) (4) biomaterial surrounds the port, providing anatomical fixation and prevention of microbial migration through tissue integration, in a manner analogous to the Dacron cuff of a tunneled catheter.

The PVAS includes the port with integrated lead-in, brake, anchor, straps, three (3) wiper seal and tissue integrating biomaterial, a custom DermaPort blade, and a polyurethane catheter with accessories necessary for tunneled catheter placement using a modified Seldinger technique.

The PVAS port allows the repositioning of the catheter tip through rotation of the catheter. This is performed without disruption of the tissue integrating biomaterial and the exit site epidermal seal is preserved. In addition, by decoupling the tissue integrating biomaterial port from the catheter, the PVAS port allows independent positioning of the catheter tip.

The fundamental technology and clinical application of the predicate PVAS is not modified by this 510(k) submission

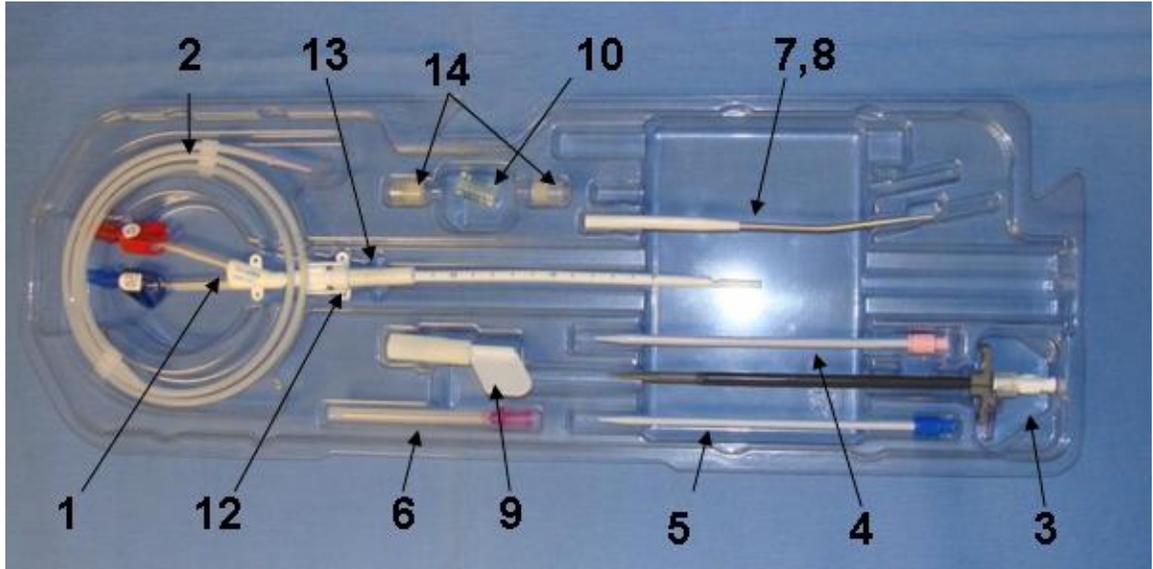
1.3 Variations

Variations of the PVAS kit are available consisting of different catheter lengths and different PVAS kit components based upon whether the kit is an “Insertion” kit or an “Exchange” kit. There are a total of 8 Catheter variations which are:

- 1) 14.5F - (24 cm, 28 cm, 32 cm, and 36 cm long)
- 2) 15.5F - (24 cm, 28 cm, 32 cm, and 36 cm long)

The Insertion PVAS kits are used during initial catheter insertion. The Insertion Kits are identical, except for the diameter/length of the catheter and length of guidewire. The Catheter is supplied with the PVAS port in place, same as the predicate PVAS. The Ported

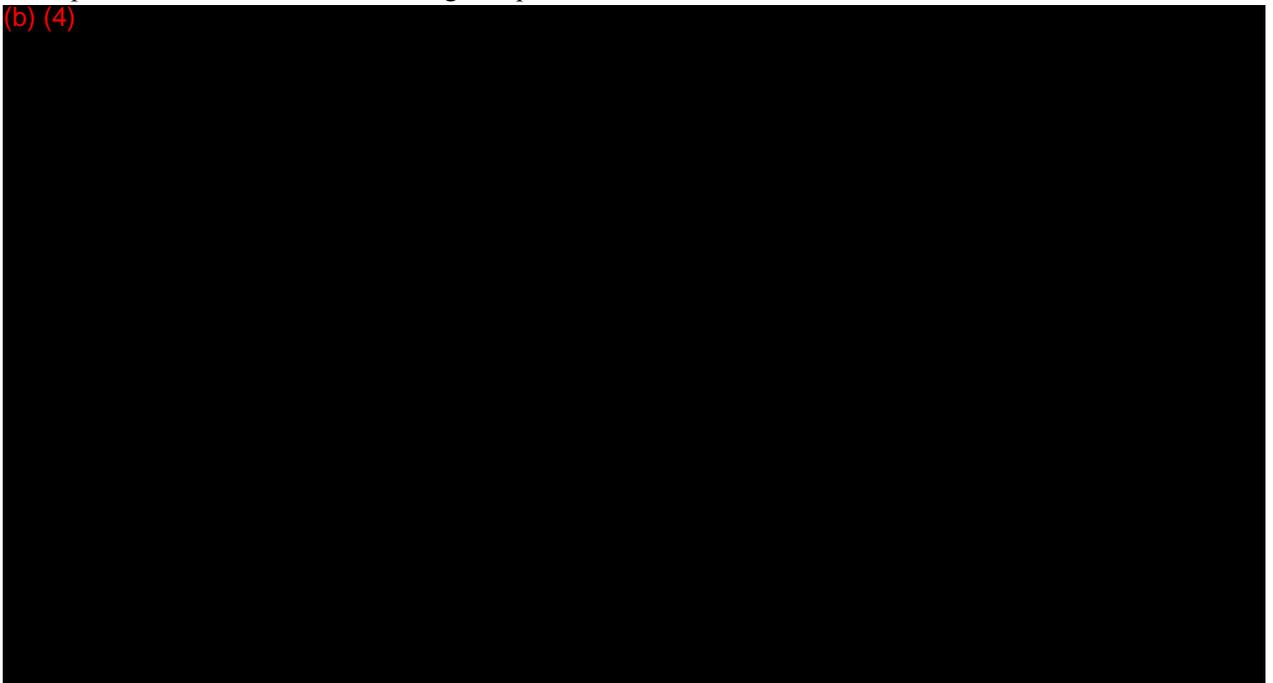
Vascular Access System consists of several components, including a surgical blade for incision at the exit site, a long-term catheter surrounded by the PVAS metal port, and various accessories associated with the insertion of tunneled catheter systems. The catheter is supplied with the PVAS port and protect cover in place. Picture 1.3-1 provides an image of the packaged PVAS.



Picture 1.3-1: Packaged PVAS Catheter (24 to 36cm lengths)

The modified DermaPort Ported Vascular Access System (PVAS) kit shown in the above pictures consists of the following components:

(b) (4)



14. Injection caps and dust covers – (modified - cap, same - dust cover)

Note: The PVAS is provided with multiple catheter lengths and diameters, with an appropriately sized guidewire.

Additional variations include Exchange Kits which are used during catheter exchange. The Exchange Kits contain only those accessories needed for exchange, which consist of a catheter, guidewire, injection caps with dust covers and replacement suture. There is an equivalent Exchange kit for each type of Insertion kit. The guidewires supplied with the Exchange kits are all 100cm and does not vary with catheter length as they do with the Insertion kits.

Attachment A contains drawings for the modified PVAS port and catheters.

1.4 Intended Use

With the exception of product name, the indication for use of the DermaPort Ported Vascular Access System is the same as the predicate PVAS cleared to market by 510(k) K071202. The indication for use is:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and the catheter is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

The FDA Indications For Use Form is provided as Attachment E.

2.0 Truthful and Accurate Statement

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87 (j))**

I certify that, in my capacity as Director of Regulatory Affairs and Quality Assurance, I believe to the best of my knowledge, that all data and information submitted in the Modified PVAS premarket notification are truthful and accurate and that no material fact has been omitted.

Jennifer Hessel, Director RA/QA

Date

[Premarket Notification (510(k)) Number]

3.0 Modified Labeling

A copy of the modified PVAS Instructions for Use is enclosed as Attachment B. For reference, Attachment C contains a copy of the PVAS Instructions for Use submitted with 510(k) K071202.

3.1 Summary of Labeling Modification

The PVAS labeling modifications that pertain to this 510(k) submission are summarized in Table 3.1 and identified by label. The modified labeling is included in Attachment B and the original labels from predicate device are included in Attachment C.

Change	Summary of Change
1. Added drawing of PVAS insertion location	(b)(4)
2. Changed drawing of PVAS in skin	
3. Protective cover instruction	
4. Removed sheath removal instructions and pictures	
5. Revised the order of insertion instructions	
6. Use of FlowGuard instructions	
7. Suture information	
8. Added a warning and picture of the symbol on PVAS port	
9. Depth markings on catheter description	
10. Added Warranty Information	
11. Added priming volumes for 15.5F Catheters	
12. Revised Flow profiles	
13. Labels for 15.5F catheters	

4.0 Specifications/Comparison of Devices

The following table provides a summary of features, modified PVAS to predicate PVAS.

Table 4.0: Comparison of PVAS			
<u>Feature</u>	<u>PVAS Under Review</u>	<u>PVAS K071202 Predicate Device</u>	<u>Comments on Comparison</u>
1. Intended Use	(b) (4)	The DermaPort Percutaneous Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and the catheter is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.	With the exception of the product name change, same, No Change
2. Indication for Use		Adult	Same, No Change
3. Contraindications		These catheters are intended for long-term vascular access only and should not be used for any other purpose other than indicated in these instructions for use.	Same, No Change
4. Insertion Method		Percutaneous	Same, No Change
5. Catheter Insertion Sites		Internal jugular vein or subclavian vein	Same, No Change
6. Sterile		Yes	Same, No Change
7. Sterilization Method		Ethylene Oxide	Same, No Change
8. Sterility Assurance Level		SAL 10 ⁻⁶	Same, No Change

Table 4.0: Comparison of PVAS

<u>Feature</u>	<u>PVAS Under Review</u>	<u>PVAS K071202 Predicate Device</u>	<u>Comments on Comparison</u>
9. Labeled Pyrogen Free	(b) (4)	Yes	Same, No Change
10. Method of Pyrogen Evaluation		FDA recognized Limulus Amoebocyte Lysate (LAL) method	Same, No Change
11. Reusable		No	Same, No Change
12. Reprocessed		No	Same, No Change
13. Patient Contacting Material		Catheter: Polyurethane PVAS Port: Titanium and Silicone	Catheter: same catheter material, with exception of larger diameter (b) (4) 14.5F) and addition of catheter depth markings, using the same ink as hub of catheter and other cleared to market (K971925) Bioflex Hemodialysis catheter with depth marking also manufactured by Martech (the contract manufacturer of the predicate and modified DermaPort catheters). PVAS Port: Same, no change
14. Environment of Use		Hospital, Clinics, Out Patient Facilities	Same, No Change
15. Packaging		Thermoplastic pouch with TYVEK header	Same, No change

Table 4.0: Comparison of PVAS

<u>Feature</u>	<u>PVAS Under Review</u>	<u>PVAS K071202 Predicate Device</u>	<u>Comments on Comparison</u>
16. Shelf Life	(b) (4)	3 years	Same, No Change as materials and process the same between 14.5F and (b) (4)
17. Dual Lumen Catheter		Yes	Same, No Change
18. Catheter Length Variations		Three (3): 14.5F, 24 cm long 14.5F, 28 cm long 14.5F, 32 cm long	(b) (4)
19. Sold as a kit		Yes	Same, No Change
20. Kit components		<ol style="list-style-type: none"> 1. Implanted Hemodialysis Catheter 2. PVAS™ Port with sheath 3. Guidewire; 0.038 inch (70 cm or 100 cm lengths) 4. 16F Dilator 5. 12F Polyethylene Dilator 6. 14F Polyethylene Dilator 7. 18 GA x 2.7" Cyrolite Introducer Needle 8. Tunneler with Tri ball tip 9. Tunneler Sleeve 10. DermaPort Surgical Blade 11. Commercially available adhesive wound dressing 12. Polycarbonate Injection Caps and 	(b) (4)

Table 4.0: Comparison of PVAS

<u>Feature</u>	<u>PVAS Under Review</u>	<u>PVAS K071202 Predicate Device</u>	<u>Comments on Comparison</u>
	(b) (4)	polypropylene dust covers	(b) (4)
21. Catheter Retention	PVAS Port	PVAS Port	

4.1 Design Control of PVAS Modification

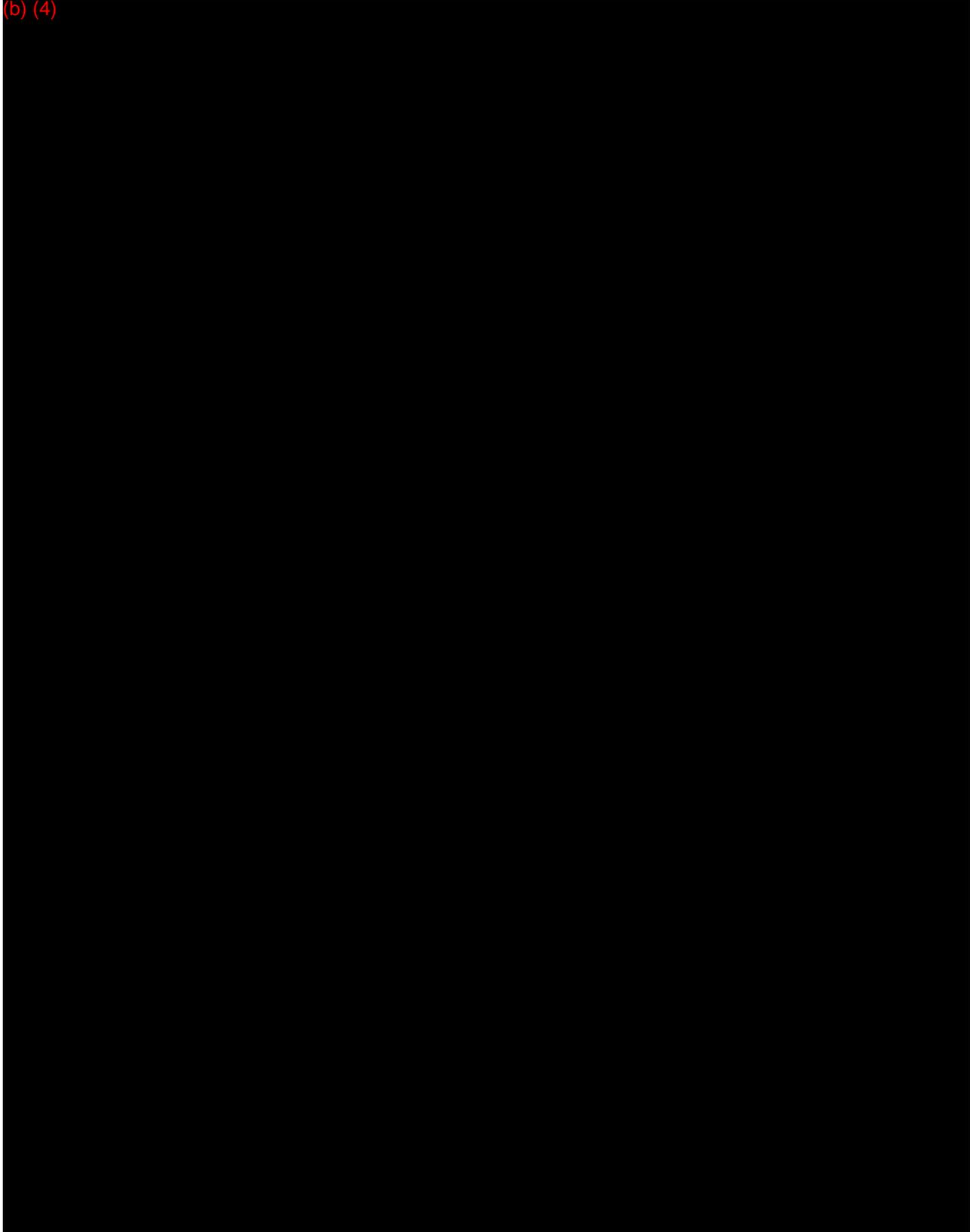
The PVAS modification was designed in compliance with the Design Control Process at DermaPort. Certification of the changes in conformance with the DermaPort Design Control process is provided in Section 6.0.

The risks of the PVAS modification are evaluated as indicated in the Risk Analysis; refer to Section 5 for details on risks associated with the design modification. A summary of the testing performed on the design and certifications to standards are discussed in Section 7.

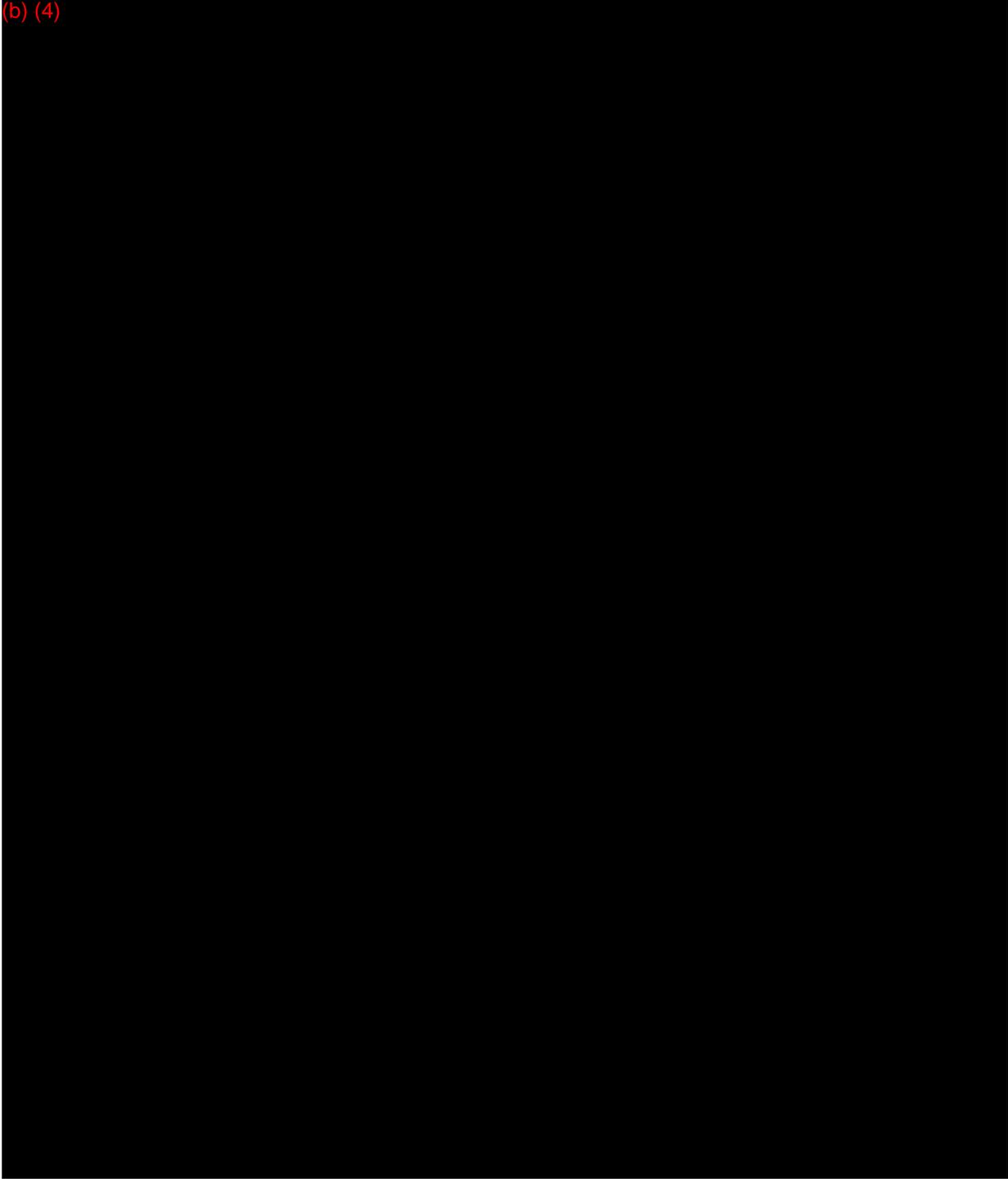
5.0 Risk Analysis

Summary of risks related to the change under review.

(b) (4)



(b) (4)



Only the changes / new risks associated with the design change are included in the Risk Analysis tables for the PVAS. Refer to **Attachment F** for the detailed risk analysis tables.

5.1 Risk Analysis Summary

As defined above there were no new significant risks were presented by the PVAS modification. The risks of the PVAS are mitigated to acceptable levels by application of labeling, selection of materials, controlled manufacturing processes, specification and verification. All resulting mitigated risks are found to be acceptable.

Risk mitigation is accomplished by application of the Design Control processes (design principals, verification of requirements) and labeling. All of the identified risks were mitigated. The Design Control required verification and validation efforts are complete. Sections 6.0 and 7.0 address verification and validation efforts. Traceability of risk mitigation is documented and filed at DermaPort in compliance with Design Control procedures.

6.0 Conformance Declaration

6.1 Performance Standards

The modification of the PVAS does not affect system compliance to the following recognized consensus standards: (b) (4) catheter meets the same performance standards as the 14.5F

The catheter component of the modified PVAS is the same supplier as the 14.5F catheter. The PVAS catheter continues to be contract manufactured by (b) (4)

(b) (4)

- a. ISO 10555-3:1996; Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters; Catheter lumen minimum flow rate,
- b. ISO 10555-1:1995; Sterile, Single-use Intravascular Catheters – Part 1: General Requirements; Catheter function and Catheter and joint bond tensile strength,
- c. ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements: Luer connections.

The packaging and subsequent sterilization by outside contractor of the kit and components is performed by DermaPort, the PVAS kits conform to the following performance standards. The changes to the components were evaluated for impact to the sterilization validation and conformance to the sterilization standard was determined to be not impacted by the changes. The packaging with the addition of new components and the additional diameter catheter was evaluated and determined that the compliance to the following standards was not affected by the changes.

- a. ANSI/AAMI/ISO 11135:2007, Medical devices—Validation and routine control of ethylene oxide sterilization.
- b. ANSI/AAMI/ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- c. AAMI/ANSI/ISO 11607-2:2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

6.2 Sterilization Declaration of Conformity

The sterilization process for the PVAS applies the FDA Recognized Consensus Standards ANSI/AAMI/ISO 11135: 2007 Medical devices—Validation and routine control of ethylene oxide sterilization. Table 6.2-1 supports the Declaration of Conformity to the ANSI/AAMI /ISO 11135 standard, reference Section 6.4.

Table 6.2-1: Conformity to FDA Recognized Consensus Standards ANSI/AAMI/ISO 11135: 2007 Medical devices—Validation and routine control of ethylene oxide sterilization	
Required Elements for a Declaration of Conformity to a Recognized Standard:	Compliance Statement:
<i>a. An identification of the applicable recognized consensus standards that were met.</i>	ANSI/AAMI/ISO 11135:2007 Medical devices— Validation and routine control of ethylene oxide sterilization ISO-10993-7:2008 Biological evaluation of medical devices-Part 7: Ethylene Oxide Sterilization Residuals
<i>b. A statement, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below.</i>	All requirements were met.
<i>c. An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).</i>	None.
<i>d. An identification, for each consensus standard, of any requirements that were not applicable to the device.</i>	None.
<i>e. A specification of any deviations from each applicable standard that were applied.</i>	No deviations to the standards were applied.
<i>f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.</i>	None.
<i>g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.</i>	Testing was performed and is documented by: (b) (4) 

6.3 Packaging

The packaging for the PVAS is a thermoplastic package with a TYVEK header that is heat sealed. A declaration of conformity to FDA Recognized Consensus Standards ASTM 4169: Performance Testing of Shipping Containers and Systems for testing performed on the modification is provided in Section 6.4. Table 6.3-1 supports the Declaration of Conformity.

Table 6.3-1: Conformity to FDA Recognized Consensus Standard	
Required Elements for a Declaration of Conformity to a Recognized Standard:	Compliance Statement:
<i>a. An identification of the applicable recognized consensus standards that were met.</i>	ASTM 4169: Performance Testing of Shipping Containers and Systems
<i>b. A statement, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below.</i>	All applicable requirements are met.
<i>c. An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).</i>	None.
<i>d. An identification, for each consensus standard, of any requirements that were not applicable to the device.</i>	None.
<i>e. A specification of any deviations from each applicable standard that were applied.</i>	No deviations to the standards were applied.
<i>f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.</i>	None.
<i>g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.</i>	Testing was be performed and documented by: (b) (4)

6.4 Declaration of Conformity

The following Declaration of Conformity is provided in support of the sterilization and packaging standards compliance information in Sections 6.2 and 6.3.



Declaration of Conformity

DermaPort Ported Vascular Access System (PVAS) with Catheter

Compliance to Sterilization and Packaging Standards

I certify that, in my capacity as Director of Regulatory Affairs and Quality Assurance of DermaPort, Inc., the sterilization validation complies with the applicable requirements of Ethylene Oxide Sterilization per ANSI/AAMI/ISO 11135:1994 Medical devices—Validation and routine control of ethylene oxide sterilization; and the packaging testing complies with the applicable requirement of ASTM 4169: Performance Testing of Shipping Containers and Systems for the DermaPort Ported Vascular Access System (PVAS).

(Signature)

Jennifer Hessel, Director RA/QA

(Printed Name, Title)

(Dated)

6.5 Design Control

The DermaPort design control process complies with the requirements specified in 21 CFR 820.30. The modifications described in this premarket notification are complete and in compliance with the DermaPort design control procedures. All risks resulting from the described modification were mitigated, designated individuals implemented verification and validation activities. The results demonstrate the predetermined acceptance criteria are met. All records are retained at DermaPort for evaluation. These results are summarized in Section 7. The declaration of conformance to the DermaPort Design Controls is provided on the following page.



Design Control Compliance Certification

I certify that in my capacity as Director of Regulatory Affairs and Quality Assurance, the modified Ported Vascular Access System (PVAS™) verification and validation complies with the DermaPort design control process. The DermaPort design control process is in compliance with the requirements specified in 21 CFR 820.30. All risks resulting from the described modifications were mitigated, designated individuals implemented verification and validation activities. The results demonstrate the predetermined acceptance criteria are met.

Jennifer Hessel, Director RA/QA

Date

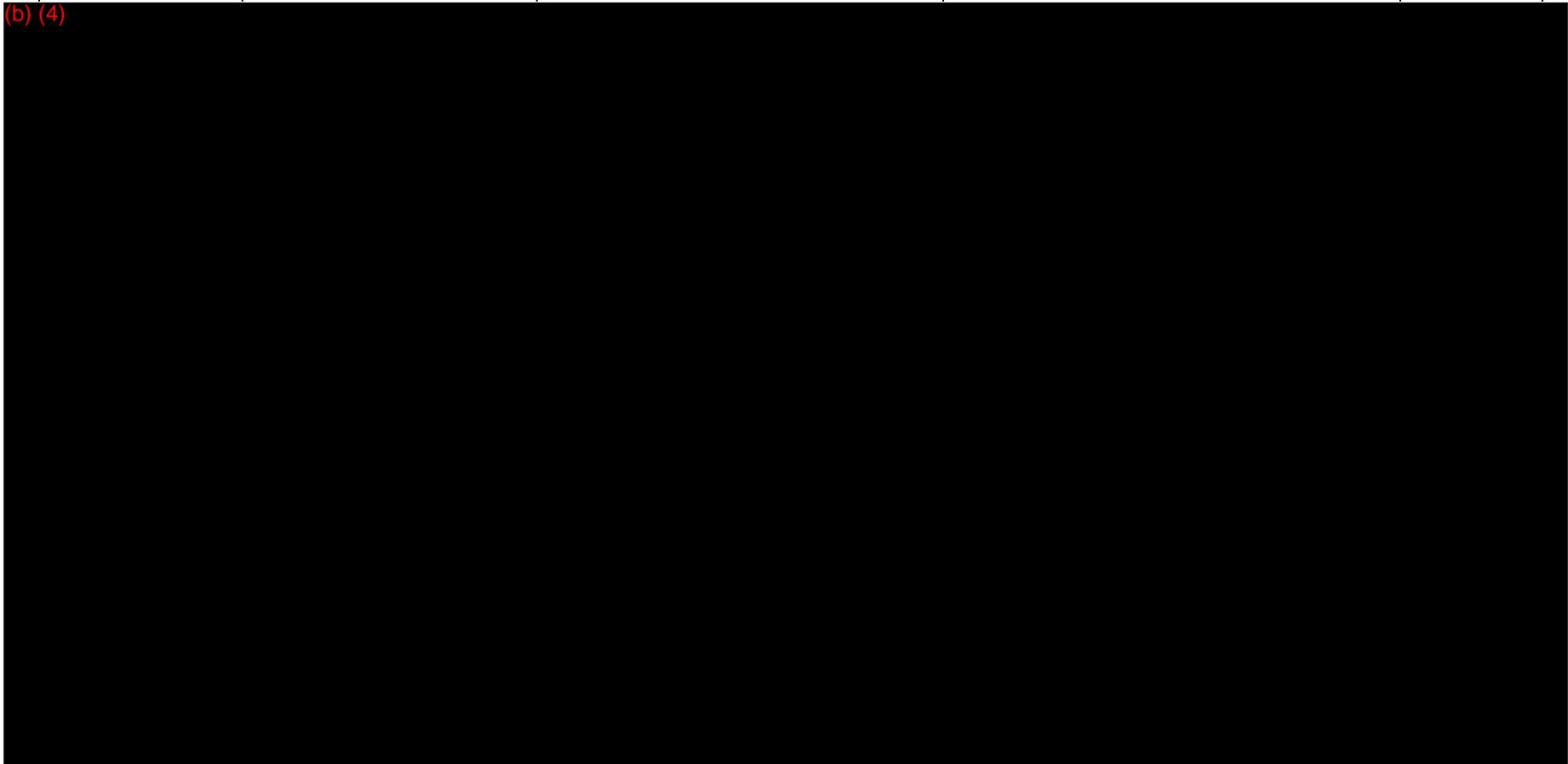
7.0 Modified Device Performance Data

The modifications to the PVAS design under review and the predicate device were evaluated using the same test methods applied to the original design with changes to accommodate the modified design. The performance testing was completed in compliance with our internal design control procedure.

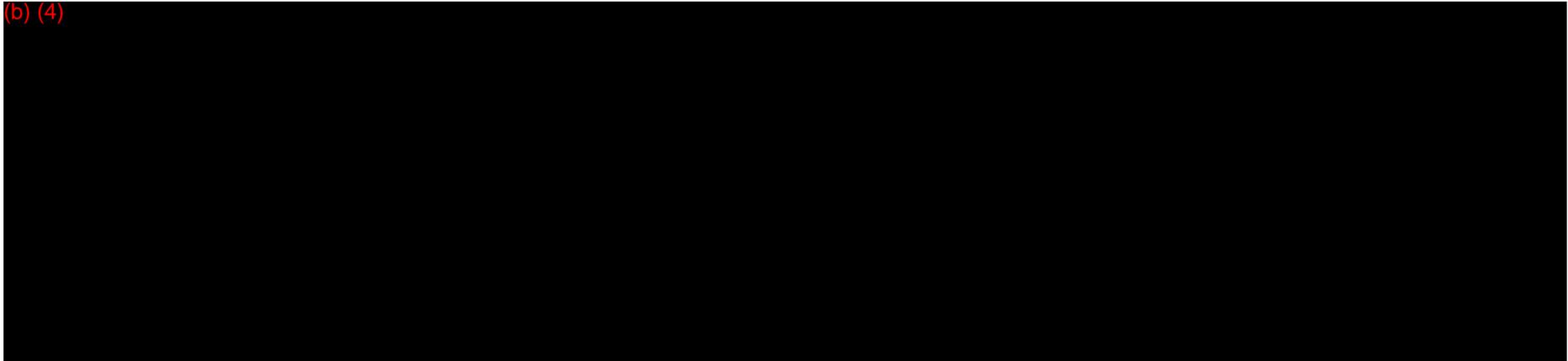
The modifications of the design or the use of these new or modified components were determined to have no impact, on device safety or effectiveness of the PVAS device, as defined in the risk analysis. The required performance testing is summarized in **Table 7.0** by specific design change. The methods applied to verify the design changes are the same as applied to the unmodified device. As indicated, the same standards are applied. Refer to Attachment H for the Standards Data Report for 510(k)s Form 3654 for all recognized standards . All reports for the testing defined are on file at DermaPort.

Table 7.0: Summarizes functional evaluations performed to support performance specification verification and safety and effectiveness of the differences.

TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device				
Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Evaluation Summary



(b) (4)



(b) (4)

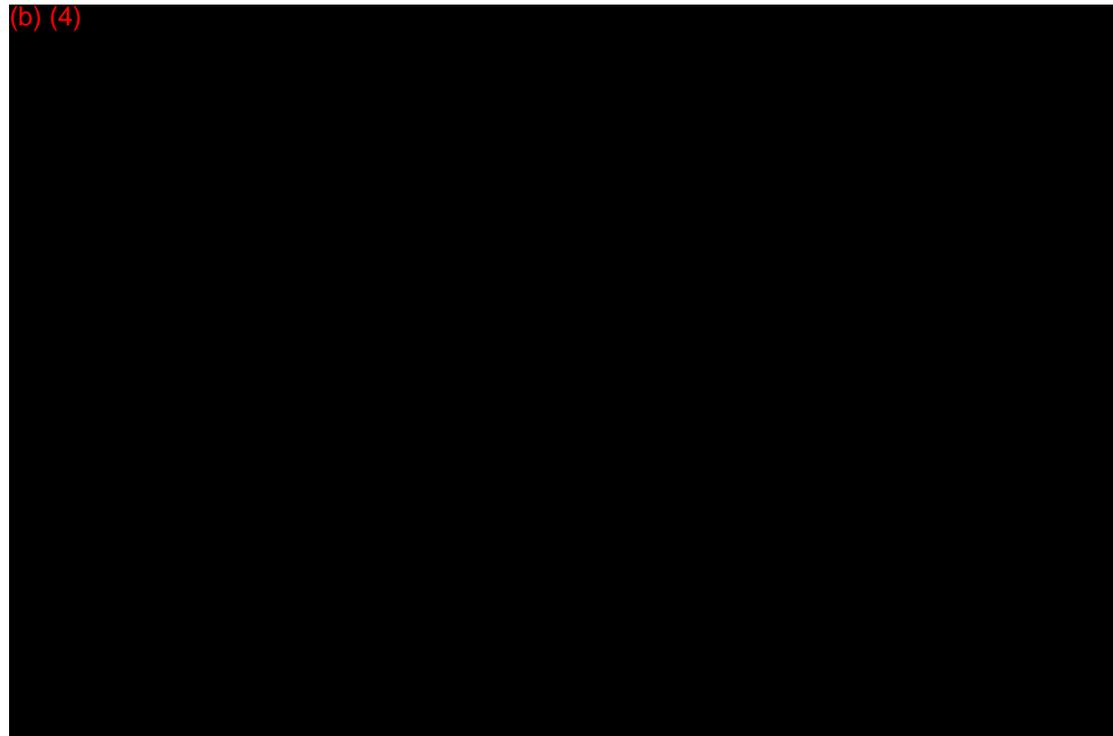
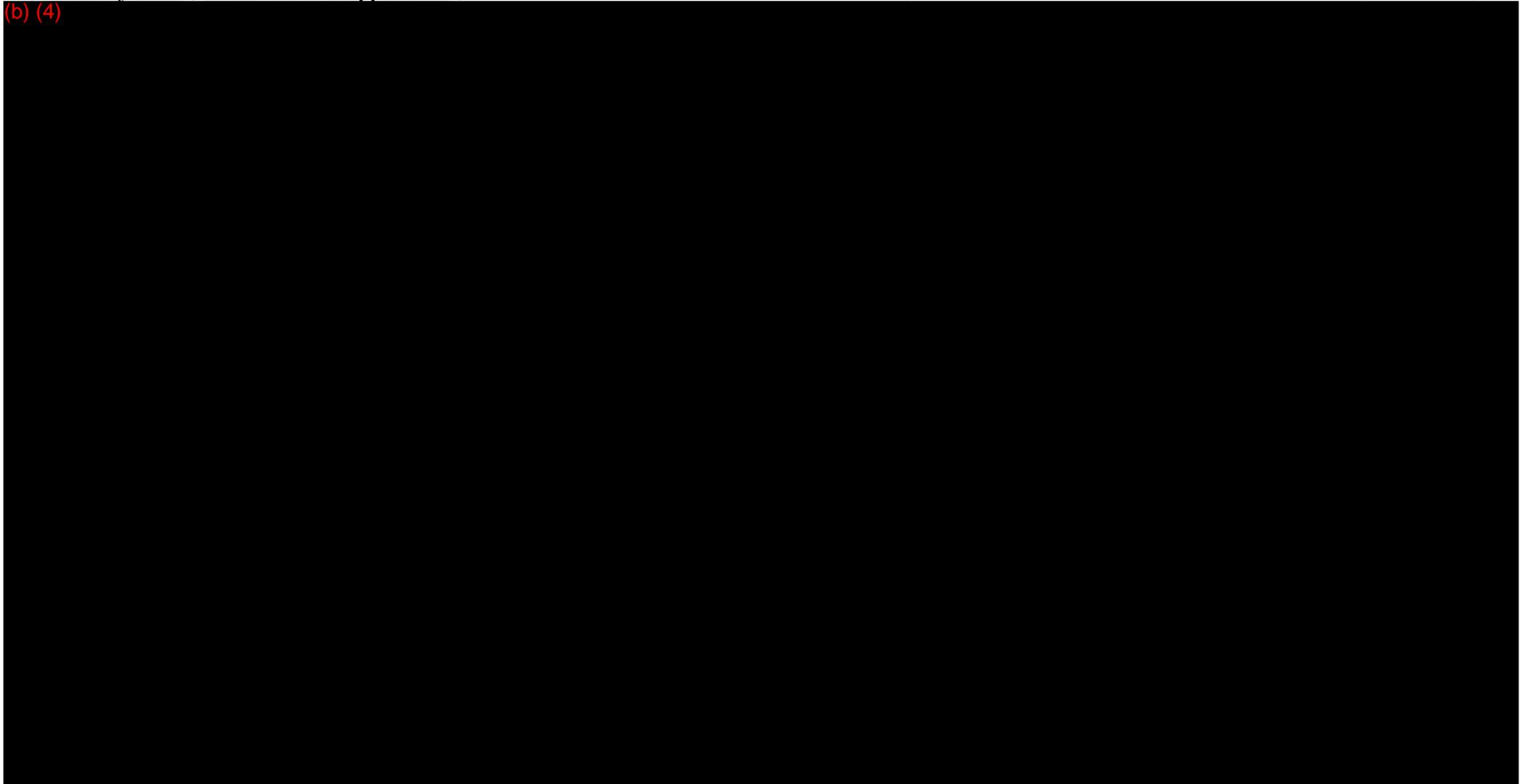


TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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(b) (4)

TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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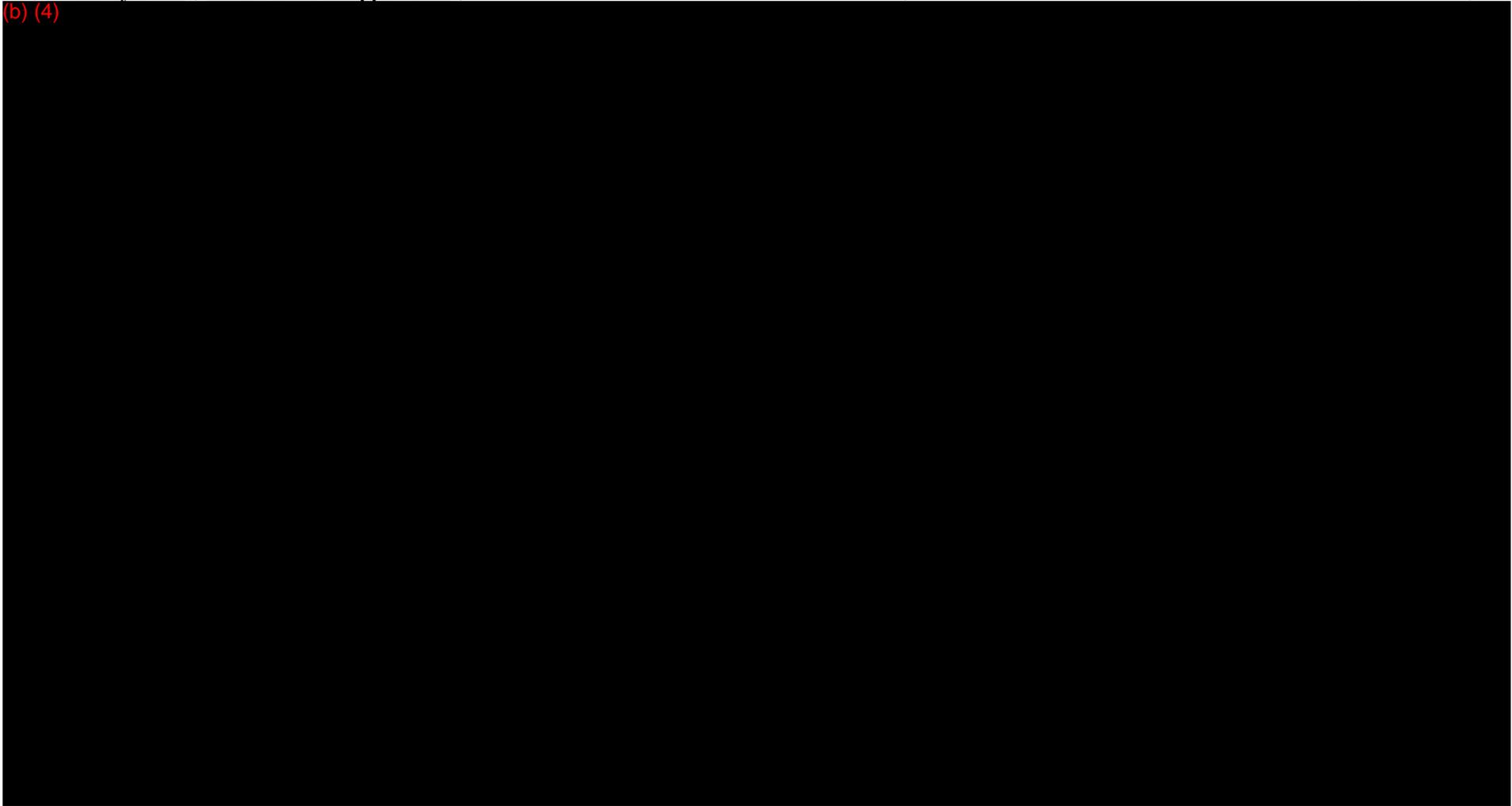


TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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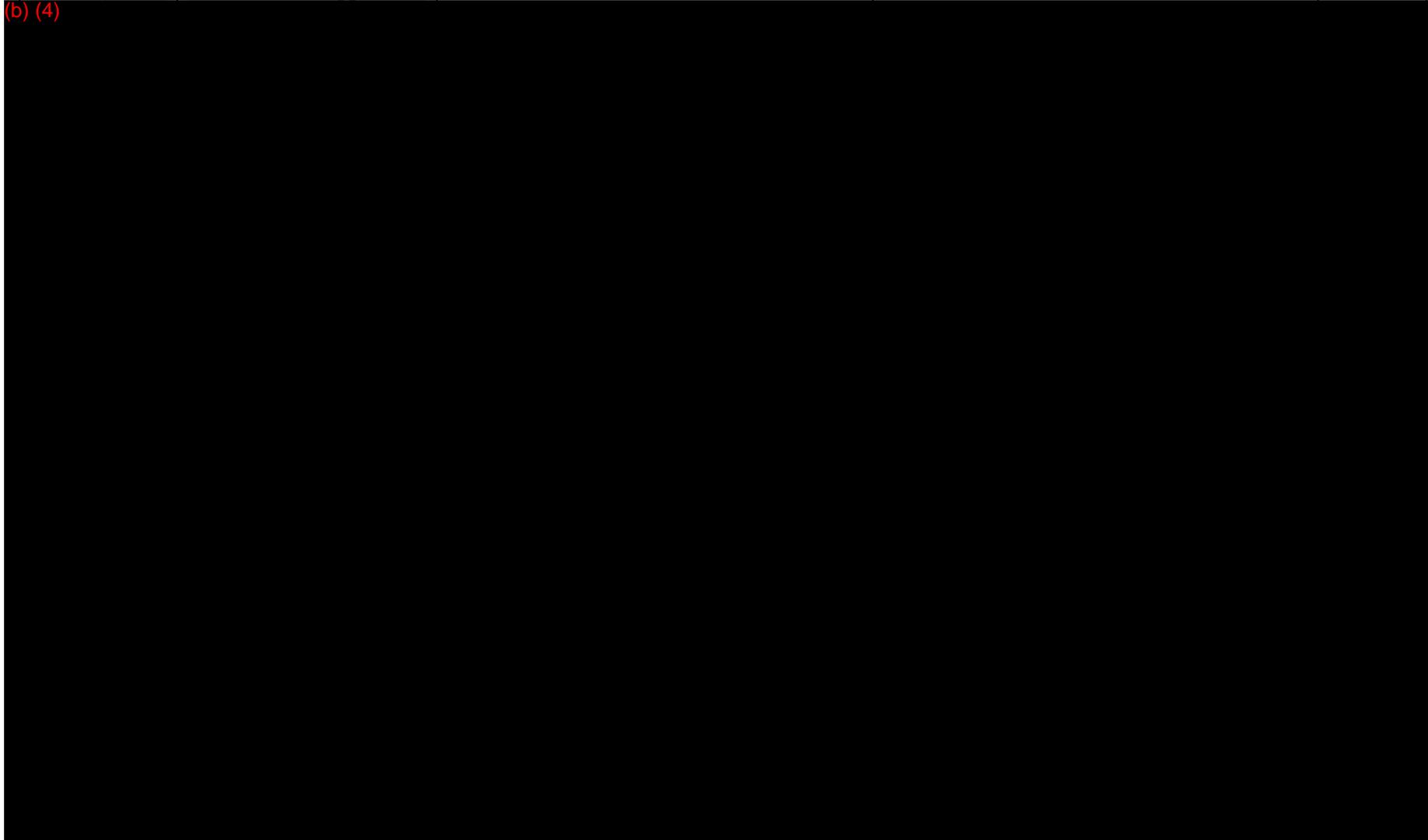


TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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(b) (4)

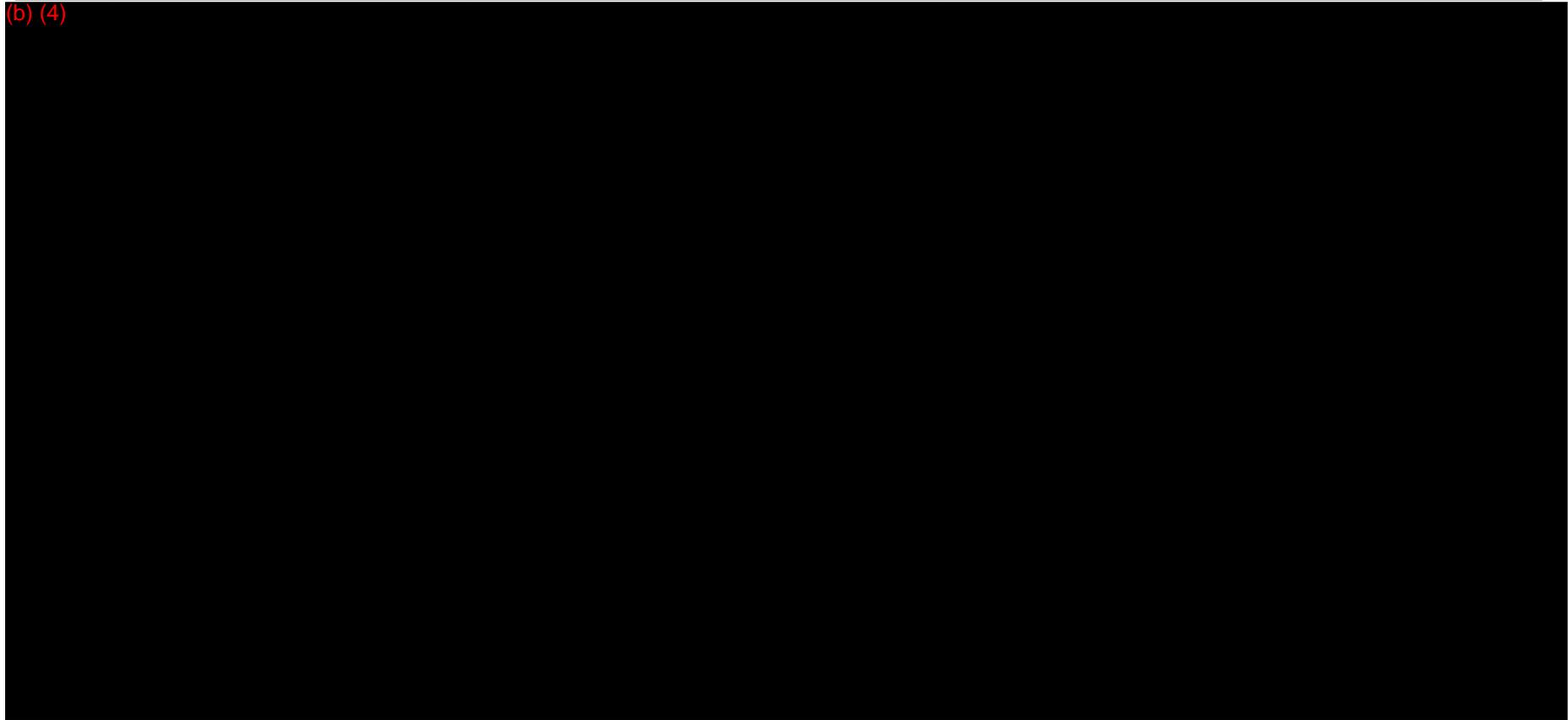


TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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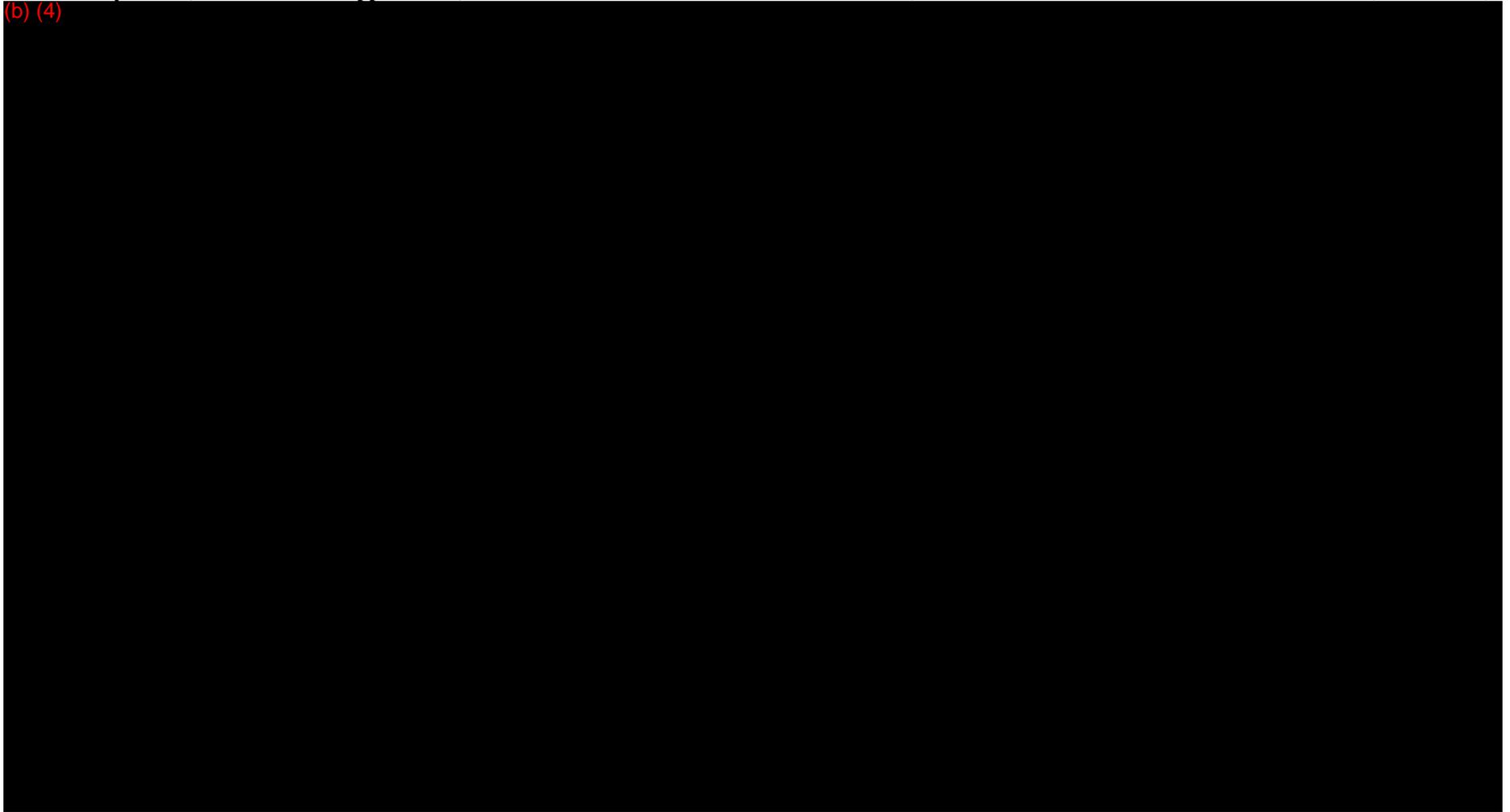


TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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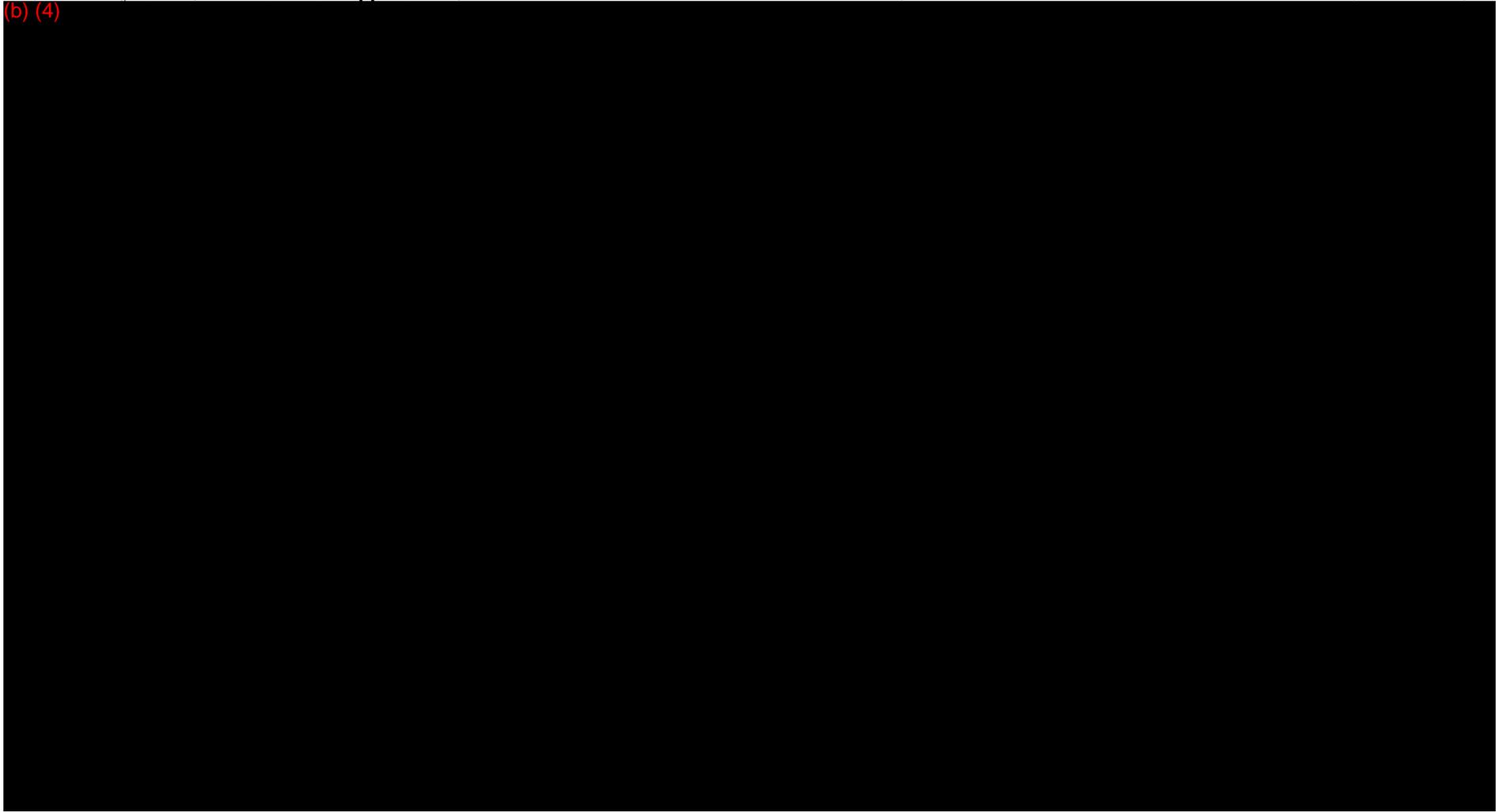
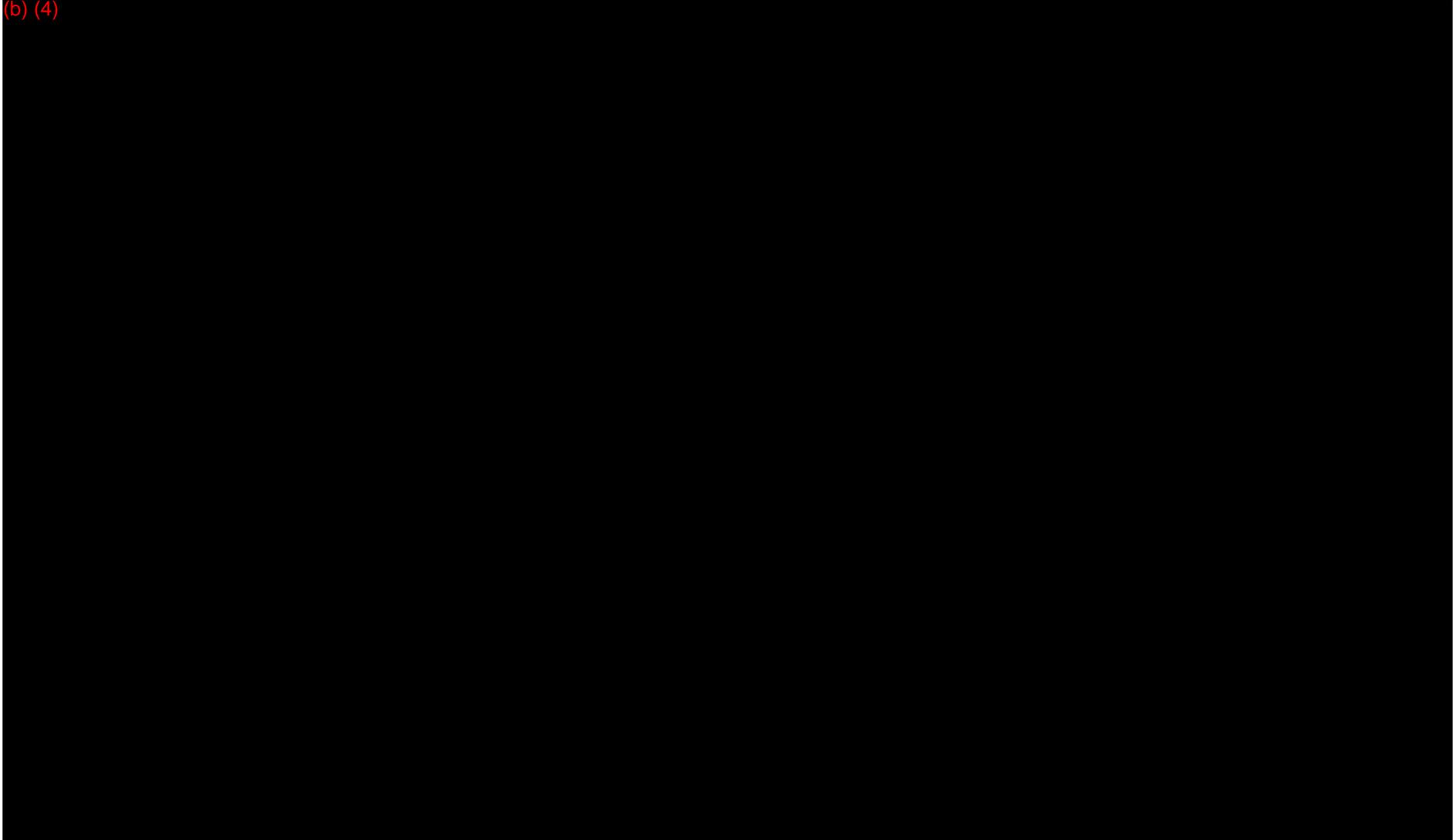


TABLE 7.0: Summary of Performance Specifications and Evaluation of Safety and Effectiveness of PVAS Device

Difference per Section 5: Risk Analysis	Change / Specification Verification and Evaluation Applied	Test Method	Results	Summary
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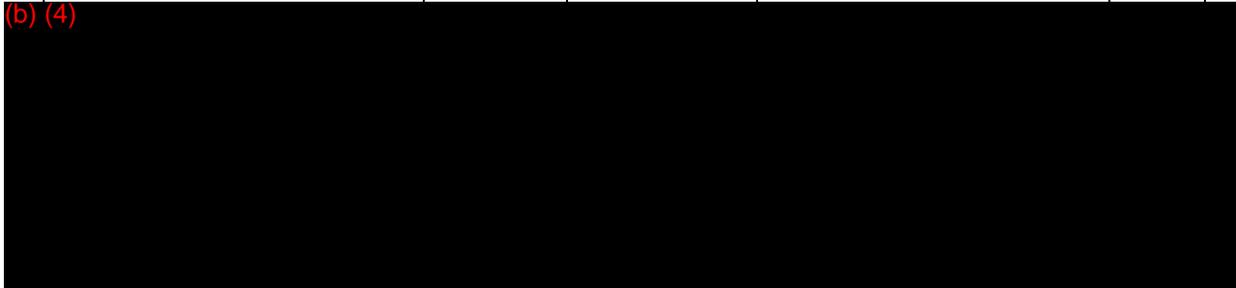


7.1 Biocompatibility

7.1.1 Catheter with Associated Components

The marked catheters and accessories are processed in the same manner as the components cleared to market by the referenced 510(k) numbers in Table 7.1.1.

Table 7.1.1-1: Regulatory Status of Components				
Description	Supplier	Supplier Part	FDA Regulatory Basis	FDA Class



With the knowledge that the catheter and associated components are supplied by the same manufacturer that holds valid 510(k) regulatory basis for these devices and components, the following material biocompatibility declaration of conformity is provided.



Declaration of Conformity

Catheter with markings and Associated Components

Material Biocompatibility

The materials of the DermaPort Catheter with Markings, FlowGuard Peelable introducer, and Suture are the same materials in formulation, processing and no other chemicals have been added (e.g., plasticizers, fillers, cleaning agents, mold release agents, etc.) as cleared to market by 510(k) K994105 (cleared 10/03/2001), K971925 (cleared 02/23/1998), K040150 (cleared 02/18/2004) and K001434 (cleared 06/12/2000).

(Signature)

Jennifer Hessel, Director RA/QA, DermaPort, Inc.

(Printed Name, Title)

(Date)

7.1.2 Injection Caps

Testing of the injection caps was conducted as guided by the FDA Recognized Consensus Standard AAMI/ANSI/ISO 10993-1:2003, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. The injections caps are defined as an external communicating device tissue contact; material biocompatibility testing was performed for prolonged contact duration. The material biocompatibility tests passed. Table 7.1.2-1 supports the Declaration of Conformity to these FDA Recognized Standards.

Table 7.1.2-1: Conformity to FDA Recognized Consensus Standards for Biocompatibility Evaluation	
Required Elements for a Declaration of Conformity to a Recognized Standard:	Compliance Statement:
<i>a. An identification of the applicable recognized consensus standards that were met.</i>	ISO-10993-5:1999 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity. ISO-10993-10:2002 Biological evaluation of medical devices-Part 10: Tests for Irritation and Sensitization. ISO-10993-11:1993 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity ASTM F756:2000 Standard Practice for Assessment of Hemolytic Properties of Materials
<i>b. A statement, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below.</i>	All applicable requirements are met.
<i>c. An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).</i>	None.
<i>d. An identification, for each consensus standard, of any requirements that were not applicable to the device.</i>	None.
<i>e. A specification of any deviations from each applicable standard that were applied.</i>	No deviations to the standards were applied.
<i>f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.</i>	None.
<i>g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.</i>	Evaluation performed and documented by: (b) (4)

The following Declaration of Conformity is provided.



Declaration of Conformity

DermaPort Ported Vascular Access System (PVAS)

Material Biocompatibility

The injection caps as part of the DermaPort Ported Vascular Access System (PVAS) kit were evaluated for compliance with the FDA Recognized Standards:

- a. ISO 10993-5:1999 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity,
- b. ISO 10993-10:2002 Biological evaluation of medical devices-Part 10: Tests for Irritation and Sensitization,
- c. ISO 10993-11:1993 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity,
- d. ASTM F756:2000 Standard Practice for Assessment of Hemolytic Properties of Materials.

All the requirements were met with a passing result.

(Signature)

Jennifer Hessel, Director RA/QA, DermaPort

(Printed Name, Title)

(Dated)

7.2 Standards Compliance

The catheter component of the PVAS will be contract manufactured (b) (4)

(b) (4)

- a. ISO 10555-3:1996; Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters; Catheter lumen minimum flow rate,
- b. ISO 10555-1:1995; Sterile, Single-use Intravascular Catheters – Part 1: General Requirements; Catheter function and Catheter and joint bond tensile strength,
- c. ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements: Luer connections.

The injection cap component of the PVAS will be supplied by (b) (4)
conformance of the injections caps to the following standard:

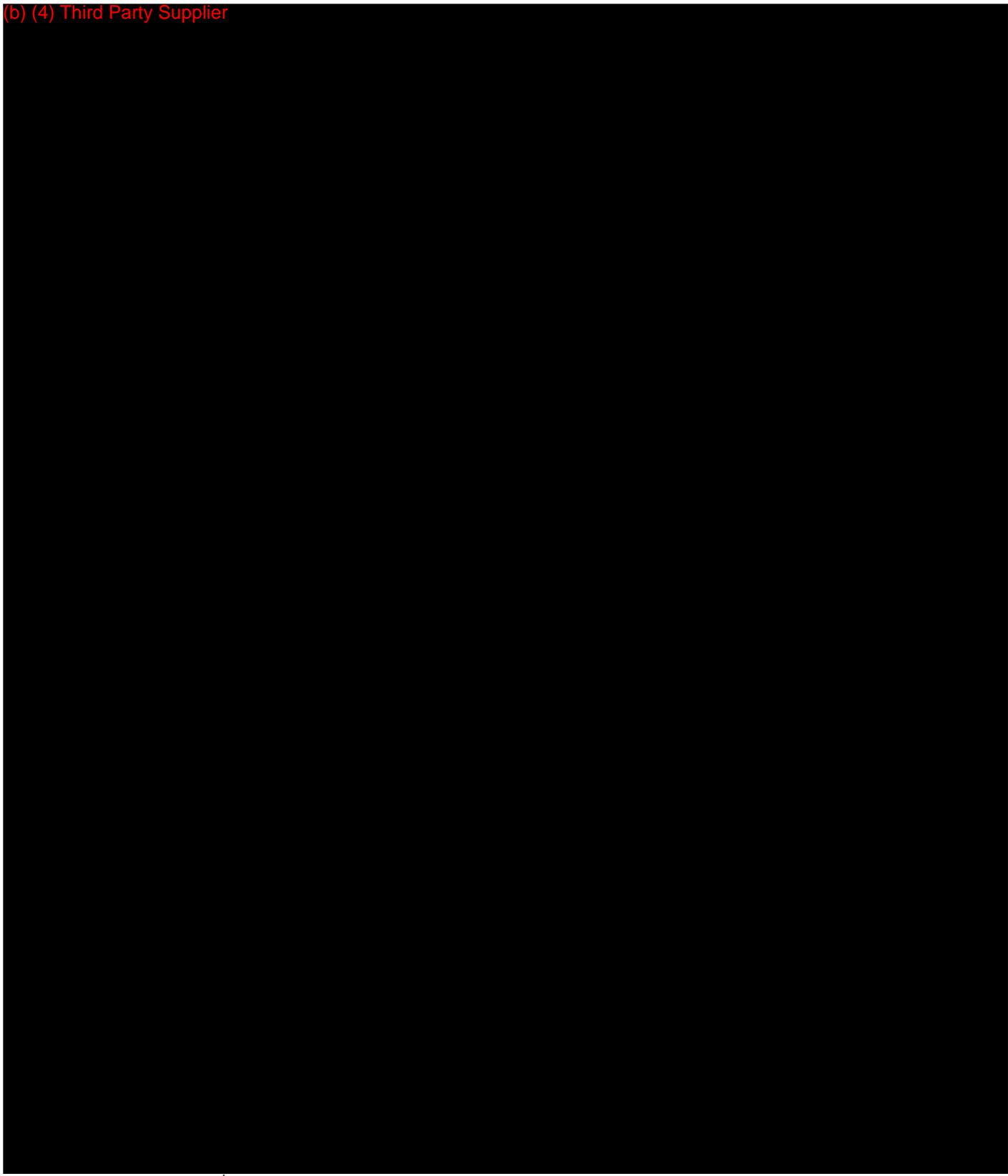
- d. ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements: Luer connections.

Table 7.2-1 documents catheter compliance with additional applicable FDA Recognized Consensus Standards.

Table 7.2-1: FDA Recognized Consensus Standard Compliance; Required Elements for a Declaration of Conformity to a Recognized Standard	
<i>a. An identification of the applicable recognized consensus standards that were met.</i>	ISO 10555-1 Sterile, Single-use Intravascular Catheters – Part 1: General Requirements ISO 10555-3 Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements: Luer connections.
<i>b. A statement, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below.</i>	All applicable requirements are met.
<i>c. An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).</i>	None.
<i>d. An identification, for each consensus standard, of any requirements that were not applicable to the device.</i>	None.
<i>e. A specification of any deviations from each applicable standard that were applied.</i>	No deviations to the standards were applied.
<i>f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.</i>	None.
<i>g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.</i>	Testing was performed and documented by: (b) (4)

The following letter from Medcomp, Martech and Qosina are provided.

(b) (4) Third Party Supplier



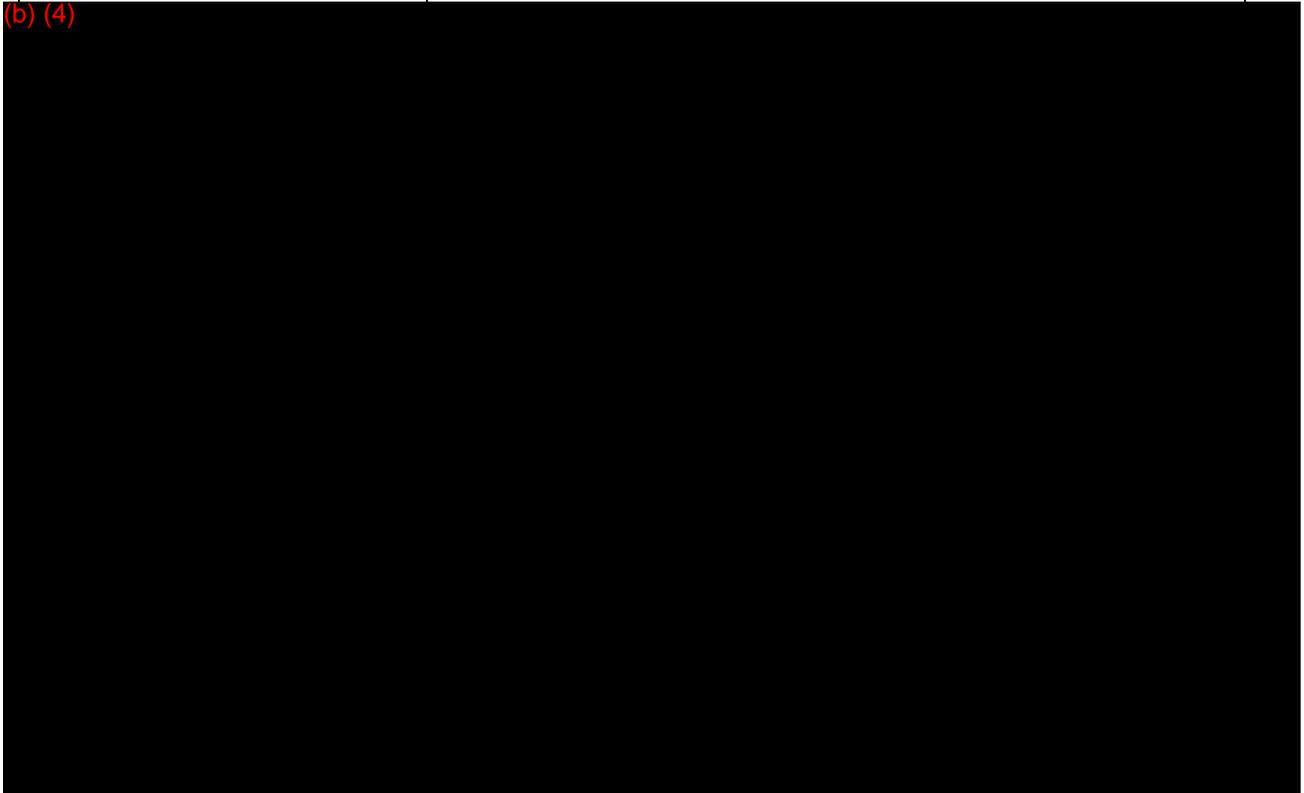
Attachment A

Drawings

	Drawing	Page
(b) (4)		A-3
		A-4
		A-6
		A-7
		A-9
		A-10
		A-11

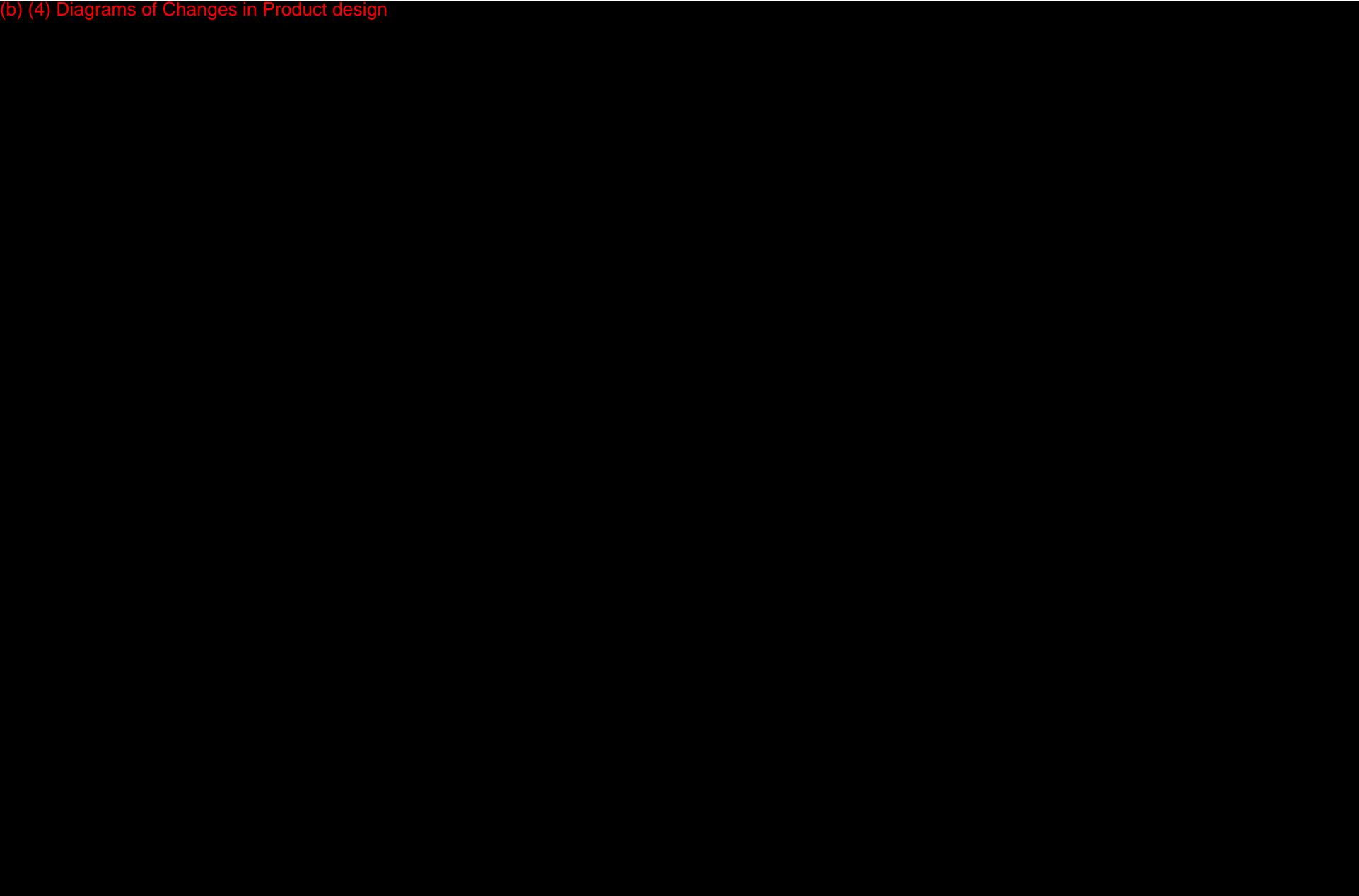
Summary of Part and Drawing Modifications

The PVAS part and drawing modifications that pertain to this 510(k) submission are summarized in the following Table and identified by part number. The part drawings are included in this section.

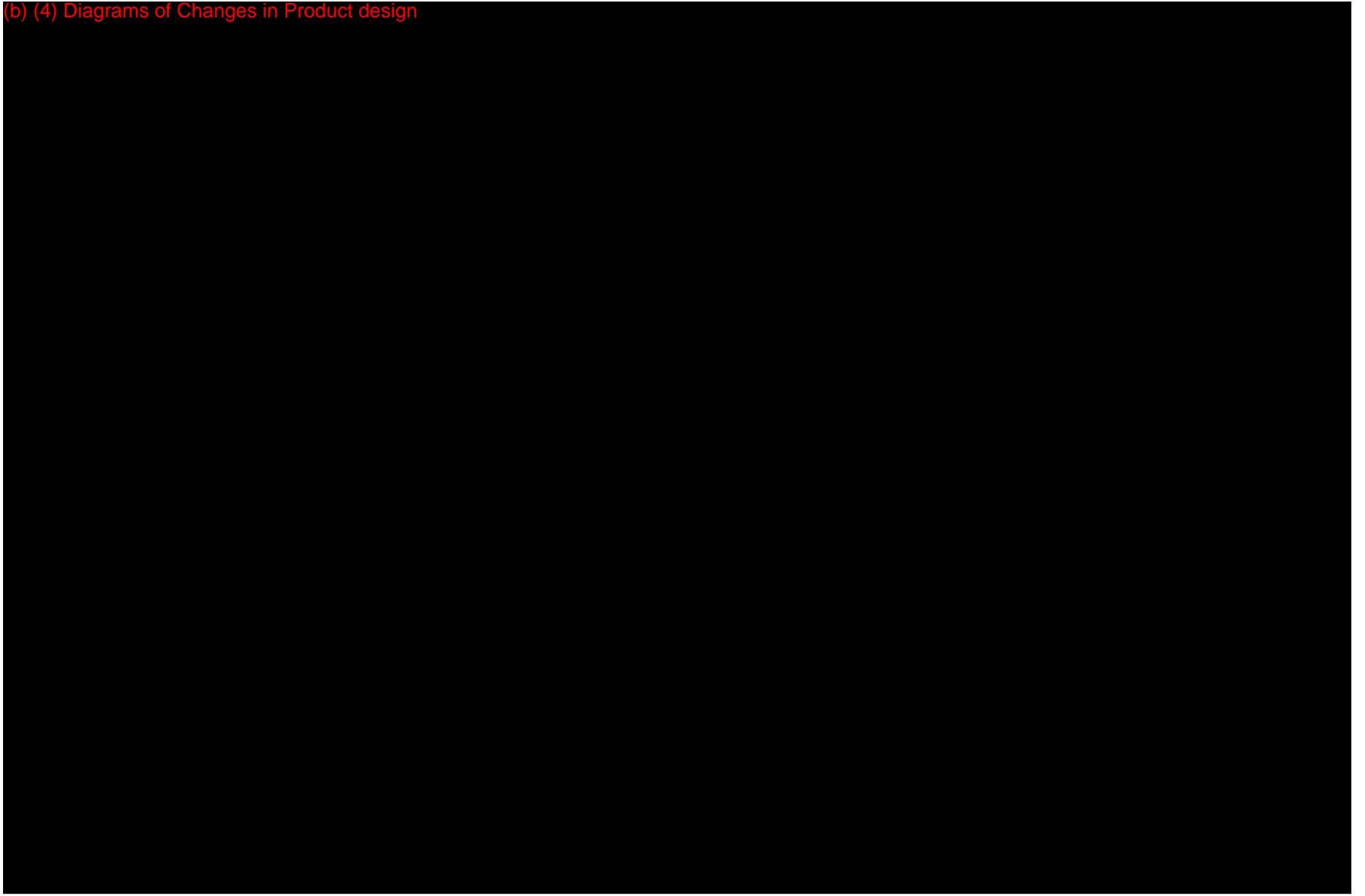
Change	Summary of Change
<p>(b) (4)</p> 	

Note: Differences/changes from the predicate device are highlighted on drawings

(b) (4) Diagrams of Changes in Product design



(b) (4) Diagrams of Changes in Product design



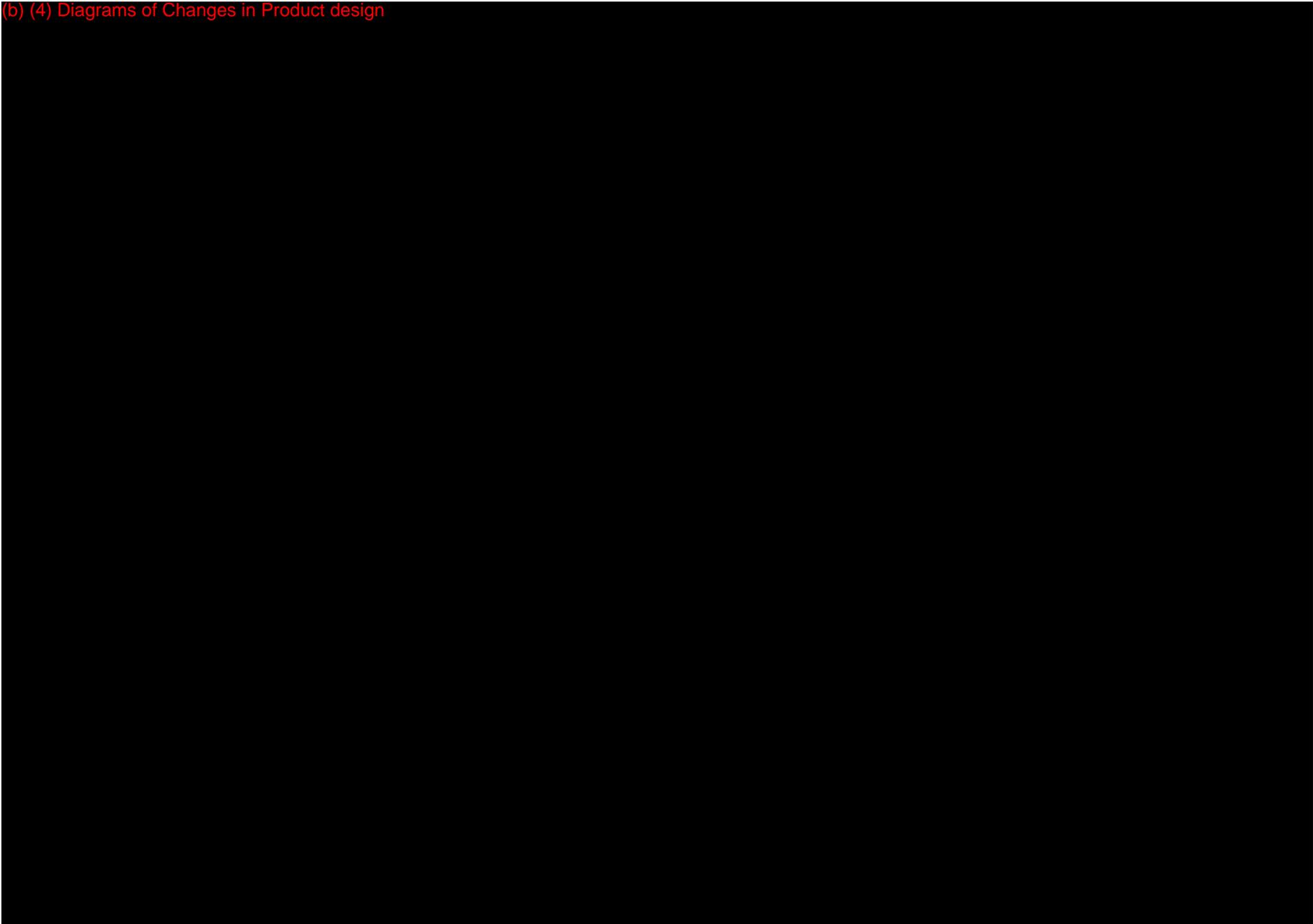
(b) (4) Diagrams of Changes in Product design



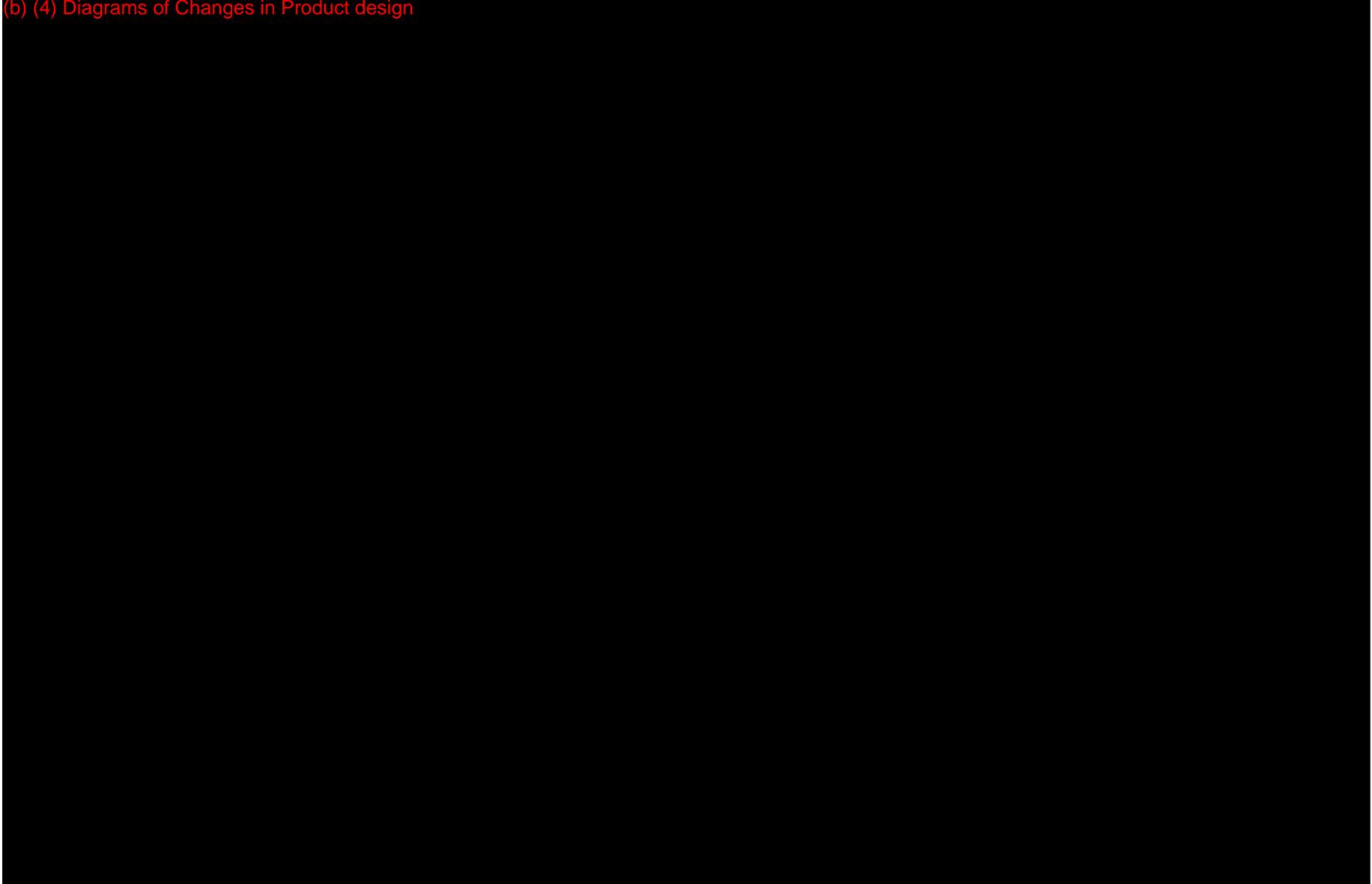
(b) (4) Diagrams of Changes in Product design



(b) (4) Diagrams of Changes in Product design



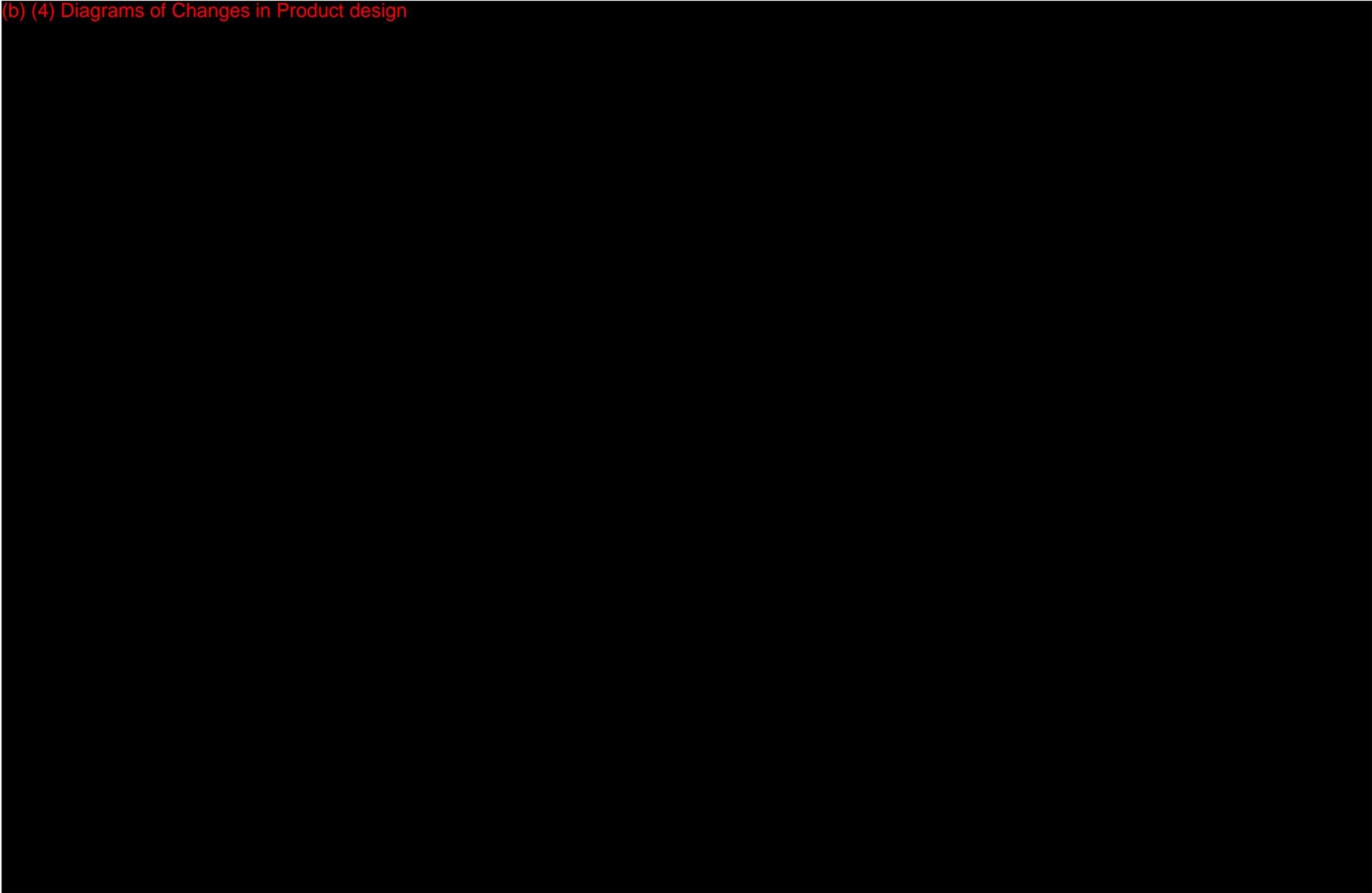
(b) (4) Diagrams of Changes in Product design



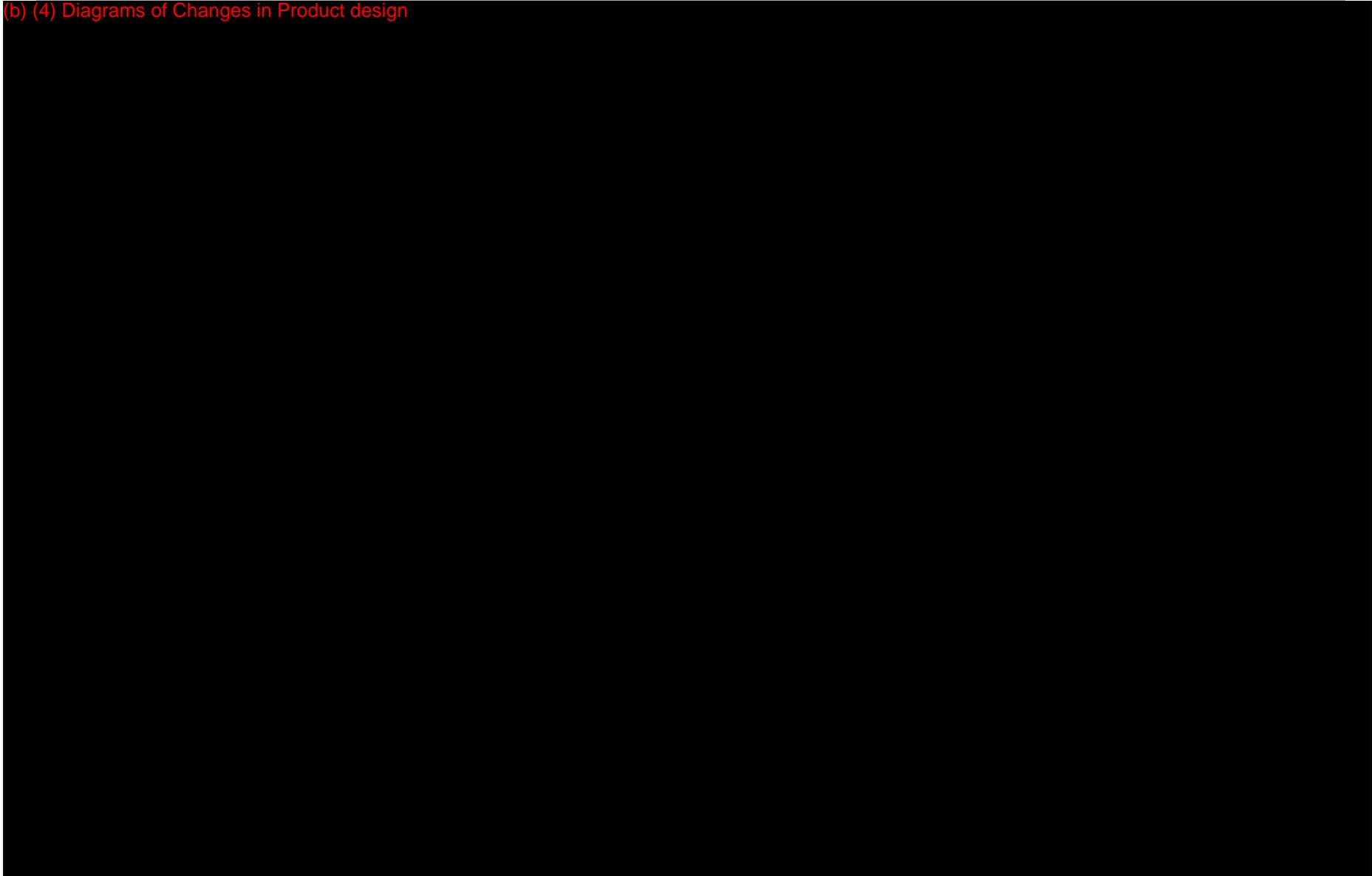
(b) (4) Diagrams of Changes in Product design



(b) (4) Diagrams of Changes in Product design



(b) (4) Diagrams of Changes in Product design



Attachment B

Modified PVAS Labeling

Labeling	Page
Instructions for Use	B-2 thru B-5
(b) (4)	



INSTRUCTIONS FOR USE PVAS™

PORTED VASCULAR ACCESS SYSTEM FOR LONG-TERM HEMODIALYSIS AND APHERESIS

Initial Catheter Insertion Catheter Removal Catheter Repositioning Catheter Exchange

DermaPort
25102 Rye Canyon Loop, Suite 110
Santa Clarita, CA 91355 USA
Tel (661) 362-7900
Fax (661) 362-7902

400-D10259
Revision A, 2009-06

INDICATIONS FOR USE

The DermaPort PVAS is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and access is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

WARNING: The catheter duration of use is limited to not longer than 12 months or as indicated by clinical practice, institution guidelines or hospital protocols.

CONTRAINDICATIONS

The PVAS is intended for long-term vascular access only and should not be used for any purpose other than those indicated in these instructions.

POTENTIAL COMPLICATIONS

Air Embolism	Mediastinal Injury
Bacteremia	Perforation of the Vessel
Brachial Plexus Injury	Pleural Injury
Cardiac Arrhythmia	Pneumothorax
Cardiac Tamponade	Retropertoneal Bleed
Central Venous Thrombosis	Right Atrial Puncture
Endocarditis	Septicemia
Exit Site Infection	Subclavian Artery Puncture
Eksanguination	Subcutaneous Hematoma
Hematoma	Superior Vena Cava Puncture
Hemorrhage	Thoracic Duct Laceration
Hemothorax	Tunnel Infection
Laceration of the Vessel	Vascular Thrombosis
Luminal Thrombosis	

WARNINGS

Do not use the PVAS if the package is opened or damaged.

Do not use the PVAS if any sign of product damage is visible.

Federal law (USA) restricts the device for sale by or on the order of a physician.

Before attempting insertion, ensure that you are familiar with the above complications and their emergency treatments.

Observe proper sterile techniques at all times when handling this accessory and all sterile items.

During the insertion procedure, do not attempt to advance the catheter if unusual resistance is encountered. Do not forcibly insert or withdraw the PVAS from the exit site.

In the rare event that a hub or connector separates from any component during insertion or use, immediately enact preventative measures to prevent blood loss or air embolism.



This PVAS is for Single Use Only.

Do not re-sterilize the PVAS by any method.

The manufacturer shall not be liable for any damages caused by reuse or reesterilization of the catheter or accessories.

Contents are sterile and non-pyrogenic in unopened, undamaged package.

Sterilized by Ethylene Oxide.



MRI INFORMATION

The PVAS was determined to be MR Conditional according to the terminology specified in the American Society of Testing and Materials (ASTM) International, Designation: F2503-05: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment ASTM Internal 2005.

Non-clinical testing demonstrated that the PVAS is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less.
- Spatial gradient magnetic field of 720-Gauss/cm or less.
- Maximum MR system reported whole body averaged specific absorption rate (SAR) or 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the PVAS produced a temperature rise of less than or equal to 0.5°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

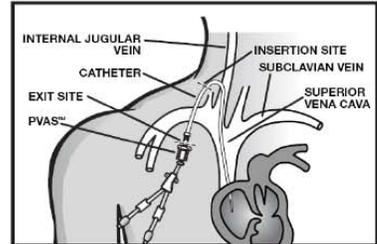
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the PVAS. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

SELECTION OF PVAS INSERTION SITE

• The catheter can be placed percutaneously using a modified Seldinger technique or open venotomy using standard surgical techniques.

• The internal jugular vein is the preferred insertion site for the catheter, as it permits easier positioning of the catheter tip in the right atrium.

The patient should be in modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.



Internal Jugular Vein: Have patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

Subclavian Vein: Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery at a point just lateral to the angle made by the clavicle and the first rib.

• Fluoroscopic or ultrasonic guidance is recommended to ensure proper tip orientation and placement within the right atrium.

WARNING: Patients requiring ventilator support are at an increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.

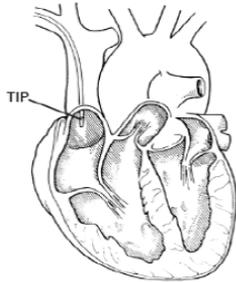
WARNING: Extended use of the subclavian vein may be associated with subclavian vein stenosis.

PVAS INSERTION PROCEDURE

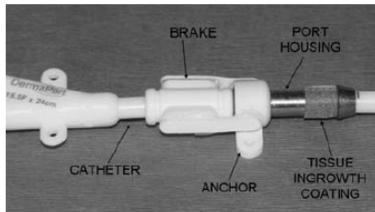
• Read instructions carefully before using this device.

1. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
2. The techniques and procedures described in these instructions for use do not represent all medically acceptable protocols. They are not intended as a substitute for the physician's experience and judgment in treating individual patients. Use standard hospital protocols when applicable.
3. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The Operating Room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.

- The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine **fluoroscopy or x-ray** should always follow the initial insertion of this catheter to confirm proper placement prior to use.



- Administer sufficient local anesthetic to completely anesthetize the PVAS insertion site on the chest wall.



- Attach a syringe to the introducer needle and insert into the target vein with ultrasonic guidance. Aspirate to ensure proper placement. Free blood flow indicates vessel entry. If the blood is bright red or pulsating return is encountered, withdraw and redirect the needle.
- Remove the syringe, and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advancer so that the end of the guidewire is visible. Insert advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

Caution: The length of the wire inserted is determined by the size of the patient. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

- Remove the needle, leaving the guidewire in the target vein. If necessary, enlarge the skin entry site using careful blunt dissection.
- Remove cover from PVAS custom blade. Use blade to make incision at the anesthetized insertion site. The blade should enter the skin at an acute angle parallel to the plane of the skin.
- Pinching or lifting of the skin at the exit site may improve access for incision.



Warning: Do not use any blade other than the PVAS blade for incising the exit site. Use of a non-approved blade may delay or prevent tissue in-growth into the PVAS mesh.

- Remove the protective cover from the PVAS port and then attach the catheter to the tunneler (a slight twisting motion may be helpful). Slide catheter tunneling sleeve over the catheter making certain that the sleeve covers the arterial holes of the catheter.

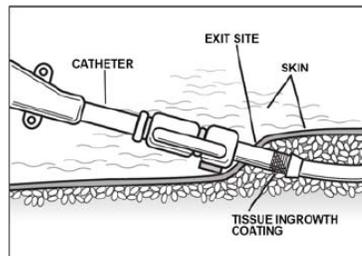
- Insert the tunneler with attached catheter into the exit site and carefully advance it through the subcutaneous tissue to the venous entry site to create a short subcutaneous tunnel. The tunnel should be made with care in order to prevent damage to surrounding vessels. Do not tunnel through muscle.

NOTE: Create a subcutaneous tunnel with a wide, gentle arc to lessen the risk of kinking.

- Carefully pull the tunneler with attached catheter through the subcutaneous tunnel. Do not push or force the catheter tubing. If resistance is encountered, careful blunt dissection may facilitate insertion.

Warning: Do not over-expand subcutaneous tissue during tunneling. Over-expansion may delay or prevent in-growth into the PVAS mesh.

- When the PVAS catheter is correctly positioned within the tunnel, disengage the PVAS brake by flipping the brake up and off the catheter.
- While holding the catheter position fixed, slide the PVAS port distally along the catheter toward the entrance site. Insert the PVAS port until the anchor reaches the incision. This places the mesh subcutaneous to the incision.



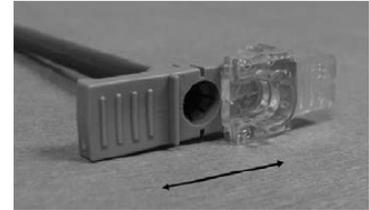
Note: The margins of the calibrated exit site may provide some resistance to insertion of the PVAS port.

- Carefully release the catheter from the tunneler with a slight twisting motion to avoid damage to the catheter.
- Irrigate the catheter with saline and then close each pinch clamp on the extension tubing to assure that the saline is not drained. Be certain that both clamps are closed.
- Slide the vein dilator onto the wire and advance it through the skin and into the vein. Be sure not to advance the guidewire. The guidewire must be stationary during the dilator advancement. If additional dilators are used, thread dilator(s) over guidewire into the vessel. Remove dilator(s) when vessel is sufficiently dilated, leave guidewire in place.

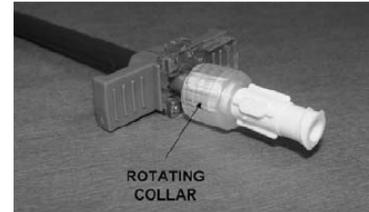
- Remove the FlowGuard® Valved Peelable Introducer assembly from the package, and remove the dilator from the sheath.

Caution: The FlowGuard Valved Peelable Introducer is design to reduce blood loss and the risk of air intake but it is not a hemostasis valve. It is not intended to create a complete two-way seal nor is it intended for arterial use.

- Slide the valve over the sheath opening.



- Reinsert the dilator through the valve and lock in place using the rotating collar.



- Slide the FlowGuard® Valved Peelable Introducer over the guidewire into the vein while maintaining the guidewire position.

- Remove the dilator and guidewire from the introducer/dilator assembly by unlocking the rotating collar and gently withdrawing the dilator from the sheath.

Caution: Damage to the vein will occur if the introducer sheath is left in place as an indwelling catheter.

Note: If the procedure does not allow the use of a valve, slide the valve away from the sheath opening.

- Insert the catheter through the valve into the sheath. To prevent kinking of the catheter, it may be necessary to advance in small steps by grasping the catheter close to the sheath. Advance the catheter so that the tip is correctly positioned in the target vein.

- Crack the sheath handle in half. Peel the non-valved side of the handle partially away from the catheter. Near the valve, hold the catheter firmly in position and pull the valve off the catheter.

- Remove the tear-away sheath by grasping both tabs and, while pulling them apart (a slight twisting motion may be helpful), and simultaneously pull the sheath out of the vessel.



Note: It is normal to experience some resistance while pulling the catheter through the slit on the valve.

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

25. Confirm proper tip placement with fluoroscopy. If necessary, adjust catheter placement under fluoroscopic observation. The distal venous tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure optimal blood flow.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

26. Attach syringes to both luer hubs and open pinch clamps. Blood should aspirate easily from both arterial and venous lumens. If either lumen exhibits excessive resistance to blood aspiration, the catheter may need to be repositioned to obtain adequate blood flows.

27. When adequate aspiration has been achieved, both lumens should be irrigated with saline using quick bolus technique.

28. Close both pinch clamps, remove the syringes, and place a cap on each luer lock hub. Avoid air embolism by keeping extensions tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

Caution: Ensure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism.

29. To maintain patency, both lumens should be filled with heparin or heparinized saline. Refer to hospital protocols or guidelines.

CATHETER SECUREMENT AND WOUND DRESSING

1. Secure the PVAS port to the skin adjacent to the exit site using two sutures to anchor the suture wings to the chest wall. **DO NOT use the polyester suture provided to secure the PVAS to the skin.**

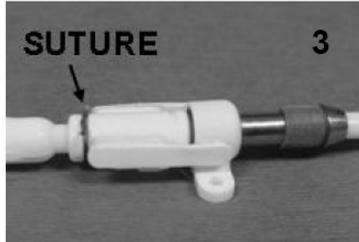
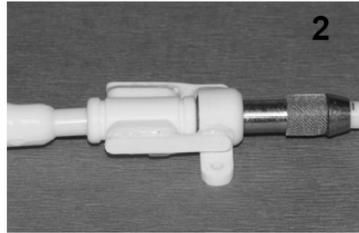
2. Do not suture the catheter tubing.

Caution: Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

3. Wipe the catheter under the PVAS brake, and flip the PVAS brake over the catheter.

4. Secure the brake to the catheter using the provided polyester suture. Tie in two loops in the proximal groove. The suture should be tied securely. (FIG 1-3).

Caution: Suture should be tight enough to be secure and to prevent the brake from being inadvertently flipped into its unengaged position.



5. Cover the PVAS and catheter exit site using an appropriate dressing. Refer to hospital policies and procedures.
6. The PVAS must remain sutured to the chest for at least 6 weeks after implantation.
7. The polyester brake suture must remain secured throughout the duration of PVAS use.
8. Attach peel-off label to the patient's medical record.
9. If the PVAS or catheter changes position or is inadvertently moved, the position of the catheter tip should be verified by fluoroscopy.

PRECAUTIONS DURING USE

1. Examine the PVAS, the catheter, and the extension tubing for possible damage before and after each use.
2. To prevent accidents, ensure the security of all caps and bloodline connections prior to and during catheter use.
3. The use of ointments on the catheter surface may cause degradation to the catheter. Do not use ointments on the catheter body.
4. Do not use sharp instruments near the extension tubing or any other part of the catheter.
5. Do not use scissors to remove dressing.
6. Use only the pinch clamps that are attached to the extension tubing. The use of any other type of clamp may cause catheter damage and lead to catheter failure.

HEMODIALYSIS TREATMENT

1. Hemodialysis should be performed under a physician's instruction.
2. The heparin locking solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspirate and discard the heparin locking solution before connecting the catheter to the hemodialysis machine.
3. All connections to catheter and extracorporeal circuits should be examined carefully before initiating hemodialysis treatment.
4. Frequent visual inspection of the extracorporeal circuit blood lines should be conducted to detect leaks in order to prevent blood loss or air embolism. If a leak is found, the catheter should be clamped immediately.

Caution: Only clamp catheter with pinch clamps attached to the extension tubes. Do not use any other type of clamping mechanism.

HEPARINIZATION

1. To maintain patency between treatments, a heparin lock should be created in each lumen of the catheter.
2. Follow hospital protocol for anticoagulant lock.
3. Draw heparin into two syringes, corresponding to the amount designated on each catheter lumen. Ensure that the syringes are free of air.
4. Verify that both pinch clamps are closed.
5. Remove caps from the luer lock hubs.
6. Secure syringe containing heparin solution to the luer hub of each extension tube.
7. Open extension clamps.
8. Aspirate to ensure that no air will be forced into the patient.
9. Inject heparin into each lumen using quick bolus technique.
10. Close pinch clamps on the extension tubes.

Caution: Pinch clamps should only be open during aspiration, flushing, and hemodialysis treatment.

11. Remove syringes.
12. Attach and secure sterile caps onto the luer hubs.
13. In most instances, no further heparin is necessary for 48-72 hours, provided the catheters have not been aspirated or flushed.

SITE CARE

1. Appropriate site care and catheter care should be determined by hospital policies or guidelines.

WARNING: DO NOT use ointments of any kind with these catheters.

2. Wound dressing must be kept clean and dry.

Caution: Patients must not swim, shower, or soak dressing while bathing.

INFECTION

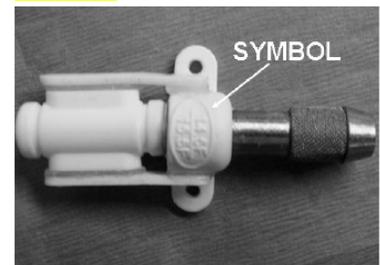
Caution: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

1. Sterile technique should always be strictly adhered to.

Note: Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate therapy.

CATHETER EXCHANGE

WARNING: A PVAS port which can accommodate both a 14.5 and 15.5F catheter is denoted by the 14.5F/15.5F symbol on the anchor. Use a 15.5F catheter only in ports labeled with the symbol as shown below.



WARNING: Only a physician familiar with the appropriate techniques should attempt the following procedures.

WARNING: Do not replace a catheter into a tunnel that is suspected to be infected.

1. Prepare the area around the catheter exit site for sterile procedure.
2. Make note of the position of the catheter using the depth marking on the catheter. The depth markings are in 1cm increments.
3. Follow hospital protocol for removal of sutures. Cut the single suture from the PVAS brake and flip the brake up and off the catheter.
4. Open the pinch clamp and quickly insert the guidewire down the venous lumen of the dual lumen catheter.
5. Under fluoroscopic observation, advance the guidewire into the inferior vena cava.
6. Apply manual compression to the subcutaneous tunnel to prevent bleeding during the catheter exchange procedure.
7. While securing the PVAS port and the brake in its disengaged position, remove the catheter through the PVAS port, maintaining the position of the guidewire tip.
8. Irrigate inside of the PVAS port with sterile saline to remove debris from interior of the PVAS port.
9. Insert the new replacement catheter over the guidewire. Carefully advance the new catheter through the PVAS port. Continue advancing the catheter over the guidewire into its proper position. The depth markings on the catheter may aid in insertion to the original location.
10. If necessary, reposition the catheter tip under fluoroscopic observation.
11. Remove the guidewire.
12. Wipe the surface of the brake contacting the catheter.
13. Wipe the catheter under the PVAS brake, and flip the PVAS brake into place over the catheter.
14. Secure the brake to the catheter using the provided polyester suture. Tie in two loops in the proximal groove. The suture should be tied securely. (FIG 1-3).

Caution: The suture should be tight enough to secure the brake and prevent it from being inadvertently flipped into its unengaged position.

15. Do not suture catheter tubing.

Caution: Care must be taken when using sharp objects or needles in close proximity to the catheter lumen. Contact with sharp objects may cause catheter failure.

16. If the catheter is not to be used immediately for treatment, follow the hospital catheter patency guidelines.

CATHETER REPOSITION

WARNING: Only a physician familiar with the appropriate techniques should attempt the following procedures.

1. Perform steps 1 through 3 under CATHETER EXCHANGE.
2. Reposition catheter to restore function. This can be done by rotating the catheter or retracting the catheter proximally (typically less than 2 cm).

WARNING: To avoid contamination of the tunnel do not advance the catheter into the PVAS port.

3. After function is restored, confirm the position of the catheter tip.
4. Secure the brake to the catheter using a suture (0-braided polyester). Tie in two loops in the proximal groove. The suture should be tied securely. (FIG 1-3).

Caution: The suture should be tight enough to secure and to prevent the brake from being inadvertently flipped into its unengaged position.

5. Perform steps 12 thru 16 under CATHETER EXCHANGE.

PVAS PORT REMOVAL

WARNING: Only a physician familiar with the appropriate techniques should attempt the following procedures.

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Palpate the catheter exit site to locate the PVAS port.
2. Administer sufficient local anesthetic to exit site and tunnel to completely anesthetize.
3. Follow hospital protocol for removal of sutures.
4. Apply manual compression to the subcutaneous tunnel to prevent bleeding during PVAS removal.
5. Pull the PVAS brake proximally to evert the PVAS mesh and in-grown tissue.
6. Dissect around the PVAS mesh using blunt and sharp dissection as needed.
7. Remove the PVAS port from the exit site.

8. Apply pressure to the proximal tunnel for approximately 10-15 minutes until bleeding stops.

9. Suture the incision and apply dressing in a manner to promote optimal wound healing.

WARRANTY

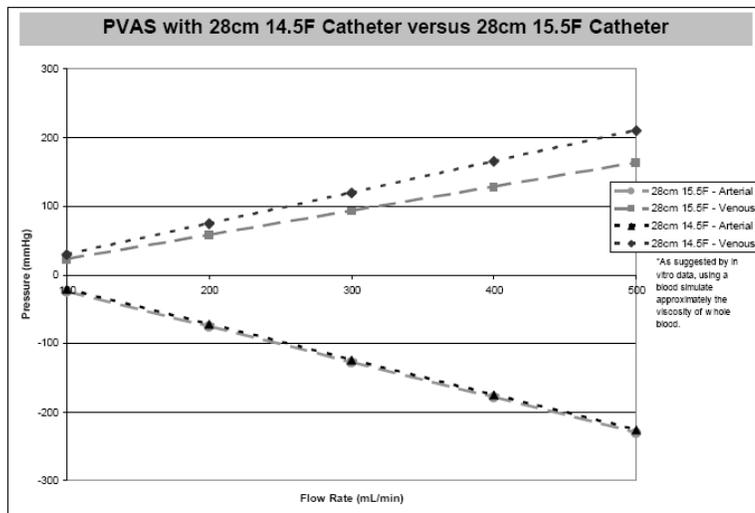
DermaPort Warrants that this product was manufactured according to applicable standards and specifications. Patient condition, clinical treatment, and product maintenance may affect the performance of this product. Use of this product should be in accordance with the instructions provided and as directed by the prescribing physician.

Because of continuing product development, prices, specifications and model availability are subject to change without notice. DermaPort reserves the right to modify its products or contents without notice.

FlowGuard® Valved Peelable Introducer is a trademark of Enpath Medical, Inc.

PRIMING VOLUMES/FLOW CURVES

CATHETER LENGTH	24 cm	28 cm	32 cm	36 cm
14.5 - Venous Volume	1.9 cc	2.0cc	2.2cc	2.4cc
14.5 - Arterial Volume	1.9 cc	2.0cc	2.2cc	2.4cc
15.5 - Venous Volume	2.0cc	2.2cc	2.4cc	2.5cc
15.5 - Arterial Volume	1.9cc	2.1cc	2.3cc	2.4cc



Representative Pouch Label 15.5F Catheter Insertion Kit

DermaPort

PVAS™

**Ported Vascular Access System
for Hemodialysis and Apheresis**

15.5F with Port, 28CM

MODEL #: HD 100 15.5 Str 28

1 Unit

1 - Catheter with Port	1 - 18GA Needle
1 - .038" X 70CM "J" Marked Guidewire	1 - Custom Blade
1 - 16F FlowGuard® Valved Introducer	1 - Tunneler with Sleeve
1 - 14F Dilator	1 - Adhesive Dressing
1 - 12F Dilator	1 - Polyester Suture
2 - Injection Caps with Covers	

Single Use Only

		Rx		
			Read Instructions for Use	
				
YYYY-MM	YYF12345			

Examine Package for damage.
Contents Sterile and Nonpyrogenic in unopened, undamaged package.
Rx Caution Federal law restricts this device for sale by or on the order of a physician

DermaPort

PVAS™ for Hemodialysis and Apheresis

1 Unit

400-D10165 Rev B Made in U.S.A.

Representative Carton Label 15.5F Catheter Insertion Kit

DermaPort

PVAS™
Ported Vascular Access System
for Hemodialysis and Apheresis
15.5F with Port, 28CM
MODEL #: HD 100 15.5 Str 28
1 Unit

1 - Catheter with Port	1 - 18GA Needle
1 - .038" X 70CM "J" Marked Guidewire	1 - Custom Blade
1 - 16F FlowGuard® Valved Introducer	1 - Tunneler with Sleeve
1 - 14F Dilator	1 - Adhesive Dressing
1 - 12F Dilator	1 - Polyester Suture
2 - Injection Caps with Covers	

STERILE EO

USA
Rx
Only

MR

! 2

YYYY-MM

25102 Rye Canyon Loop, Suite 110
Santa Clarita, CA 91355 USA
Tel: (661) 362-7900
Fax: (661) 362-7902

DermaPort

PVAS™ for
Hemodialysis
and Apheresis

LOT
YYF12345

28 cm
15.5F
Straight
Insertion

400-D10169 Rev B Made in U.S.A.

Attachment C

Unmodified PVAS Labeling

Labeling	Page
Instructions for Use	C-2 thru C-5
Pouch Labels	C-8 thru C-9



INSTRUCTIONS FOR USE PVAS™

PORTED VASCULAR ACCESS SYSTEM FOR LONG-TERM HEMODIALYSIS AND APHERESIS

Initial Catheter Insertion Catheter Removal Catheter Repositioning Catheter Exchange

DermaPort
25102 Rye Canyon Loop, Suite 110
Santa Clarita, CA 91355 USA
Tel (661) 362-7900
Fax (661) 362-7902

400-D10082
Revision E, 2008-04

Because of continuing product development, prices, specifications and model availability are subject to change without notice. DermaPort reserves the right to modify its products or contents without notice.

INDICATIONS FOR USE

The DermaPort PVAS is indicated for long-term vascular access for hemodialysis and apheresis. The system is inserted percutaneously and is typically placed in the internal jugular vein. The subclavian vein is an alternate insertion site.

WARNING: The catheter duration of use is limited to not longer than 12 months or as indicated by clinical practice, institution guidelines or hospital protocols.

CONTRAINDICATIONS

The PVAS is intended for long-term vascular access only and should not be used for any purpose other than those indicated in these instructions.

MRI INFORMATION

The PVAS was determined to be MR Conditional according to the terminology specified in the American Society of Testing and Materials (ASTM) International, Designation: F2503-05: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment ASTM Internal 2005.

Non-clinical testing demonstrated that the Ported Vascular Access System is MR Conditional. A Patient with this implant can be scanned safely immediately after placement under the following condition:

- Static magnetic field of 3-Tesla or less.
- Spatial gradient magnetic field of 720-Gauss/cm or less.
- Maximum MR system reported whole body averaged specific absorption rate (SAR) or 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the Ported Vascular Access System produced a temperature rise of less than or equal to 0.5°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Ported Vascular Access System.

Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

POTENTIAL COMPLICATIONS

Air Embolism	Mediastinal Injury
Bacteremia	Perforation of the Vessel
Brachial Plexus Injury	Pleural Injury
Cardiac Arrhythmia	Pneumothorax
Cardiac Tamponade	Retroperitoneal Bleed
Central Venous Thrombosis	Right Atrial Puncture
Endocarditis	Septicemia
Exit Site Infection	Subclavian Artery Puncture
Exsanguination	Subcutaneous Hematoma
Hematoma	Superior Vena Cava Puncture
Hemorrhage	Thoracic Duct Laceration
Hemothorax	Tunnel Infection
Laceration of the Vessel	Vascular Thrombosis
Luminal Thrombosis	

WARNINGS

Do not use the PVAS if the package is opened or damaged.

Do not use the PVAS if any sign of product damage is visible.

Before attempting insertion, ensure that you are familiar with the above complications and their emergency treatments.

Observe proper sterile techniques at all times when handling this accessory and all sterile items.

During the insertion procedure, do not attempt to advance the accessory if unusual resistance is encountered. Do not forcibly insert into or withdraw the PVAS from the exit site.

In the rare event that a hub or connector separates from any component during insertion or use, immediately enact preventative measures to prevent blood loss or air embolism.

Federal law (USA) restricts the device for sale by or on the order of a physician.

This PVAS is for Single Use Only. 

Do not re-sterilize the PVAS by any method.

The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of the catheter or accessories.

Contents are sterile and non-pyrogenic in unopened, undamaged package.

Sterilized by Ethylene Oxide.



SELECTION OF PVAS INSERTION SITE

- The catheter can be placed percutaneously using a modified Seldinger technique or open venotomy using standard surgical techniques.
- Fluoroscopic or ultrasonic guidance is recommended to insure proper tip orientation and placement within the right atrium.
- The patient should be in modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.
- The internal jugular vein is the preferred insertion site for the catheter, because it permits easier positioning of the catheter tip in the right atrium.

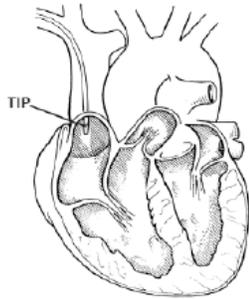
Internal Jugular Vein: Have patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

Subclavian Vein: Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery at a point just lateral to the angle made by the clavicle and the first rib.

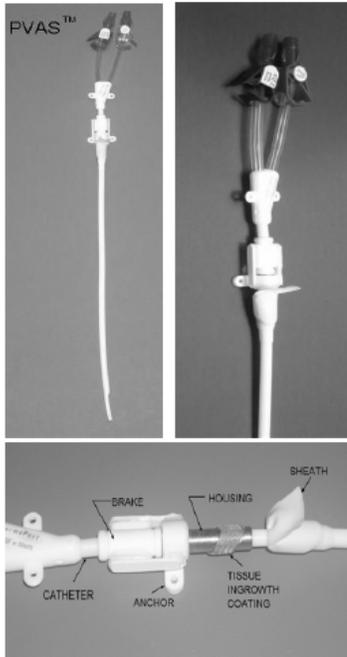
WARNING: Patients requiring ventilator support are at an increased risk of pneumothorax during subclavian vein cannulation, which may cause complications. Extended use of the subclavian vein may be associated with subclavian vein stenosis.

PVAS INSERTION PROCEDURE

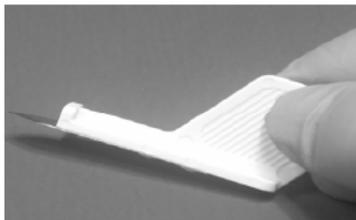
- Read instructions carefully before using this device.
 - The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
 - The techniques and procedures described in these instructions for use do not represent all medically acceptable protocols. They are not intended as a substitute for the physician's experience and judgment in treating individual patients. Use standard hospital protocols when applicable.
1. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The Operating Room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.
 2. The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.



3. Administer sufficient local anesthetic to completely anesthetize the PVAS insertion site on the chest wall.



4. Use PVAS custom blade to make incision at the anesthetized insertion. The blade should enter the skin at an acute angle parallel to the plane of the skin. Pinching or lifting of the skin at the exit site may improve access for incision.



Warning: Do not use any blade other than the PVAS blade for incising the exit site. Use of a non-approved blade may delay/prevent tissue in-growth into the PVAS mesh.

5. Make a second incision at the anticipated site for inserting the PVAS catheter into the internal jugular or subclavian vein.

6. Attach the catheter to the tunneler (a slight twisting motion may be helpful). Slide catheter tunneling

sleeve over the catheter making certain that the sleeve covers the arterial holes of the catheter.

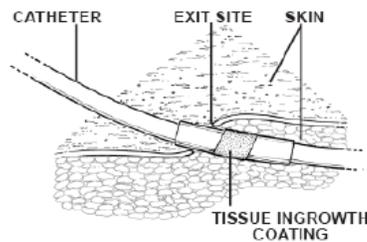
7. Insert the tunneler with attached catheter into the exit site and carefully advance it through the subcutaneous tissue to the venous entry site to create a short subcutaneous tunnel. The tunnel should be made with care in order to prevent damage to surrounding vessels. Do not tunnel through muscle.

NOTE: Create a subcutaneous tunnel with a wide, gentle arc to lessen the risk of kinking. The tunnel should be sufficiently short to keep the Y-hub of the catheter from entering the exit site.

8a. Carefully pull the tunneler with attached catheter through the subcutaneous tunnel. Do not push or force the catheter tubing. If resistance is encountered, careful blunt dissection may facilitate insertion.

Warning: Do not over-expand subcutaneous tissue during tunneling. Over-expansion may delay / prevent in-growth into the PVAS mesh.

- When the PVAS catheter is correctly positioned within the tunnel, disengage the PVAS brake by flipping the brake up and off the catheter.
- While holding the catheter position fixed, slide the PVAS port distally along the catheter toward the catheter entrance site. Insert the PVAS port with its protective sheath until the tab of the sheath reaches the incision. The anchor should be approximately 0.5cm from the incision. This places the mesh immediately subcutaneous to the incision.



Note: The margins of the calibrated incision may provide some resistance to insertion of the PVAS port in its protective sheath.

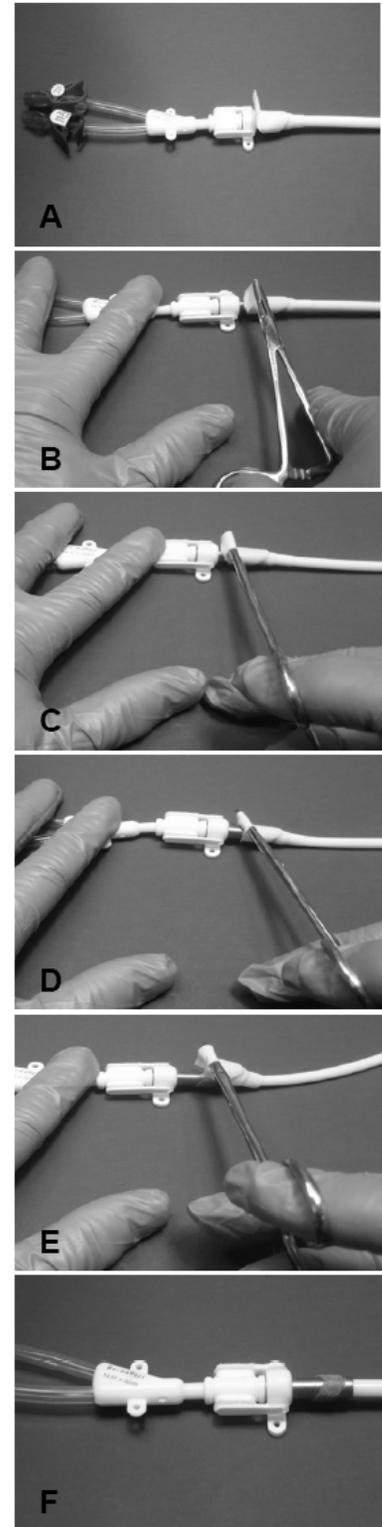
Caution: Do not insert the PVAS port into subcutaneous tunnel without the protective sheath.

8b. Use hemostats to grasp the end of the tab on the sheath.

Caution: Do not use serrated or curved hemostats.

8c. Hold the PVAS port in place and peel away the protective sheath by winding the hemostats away from the incision (Figures A-F)

Caution: Insure that the entire sheath is removed.



9. Carefully release the catheter from the tunneler with a slight twisting motion to avoid damage to the catheter.

10. Close each pinch clamp on the extension tubing while flushing the catheter lumen with saline. Be certain that both clamps are closed.

11. Attach a syringe to the introducer needle and insert into the target vein with ultrasonic guidance. Aspirate to insure proper placement. Free blood flow indicates vessel entry. If the blood is bright red or pulsating return is encountered, withdraw and redirect the needle.

12. Remove the syringe, and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advancer so that the end of the guidewire is visible. Insert advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

13. Remove the needle, leaving the guidewire in the target vein. If necessary, enlarge the skin entry site using careful blunt dissection.

14. Slide the vein dilator onto the wire and advance it through the skin and into the vein. Be sure not to advance the guidewire. The guidewire must be stationary during the dilator advancement. If additional dilators are used, thread dilator(s) over guidewire into the vessel. Remove dilator(s) when vessel is sufficiently dilated, leave guidewire in place.

15. Slide the introducer sheath with dilator over the guidewire into the vein while maintaining the guidewire position.

Caution: Damage to the vein will occur if the introducer sheath is left in place as an indwelling catheter.

16. Withdraw dilator and guidewire, leaving the introducer sheath in place.

17. Insert the distal tip of the catheter into the introducer sheath and advance the catheter so that the tip is correctly positioned in the target vein.

18. Remove the tear-away sheath by grasping both tabs and, while pulling them apart (a slight twisting motion may be helpful), simultaneously pull the sheath out of the vessel.

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

19. Confirm proper tip placement with fluoroscopy. If necessary, adjust catheter placement under fluoroscopic observation. The distal venous tip should be positioned at the level of the caval-atrial junction or into the right atrium to ensure optimal blood flow.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

20. Attach syringes to both luer hubs and open pinch clamps. Blood should aspirate easily from both arterial and venous lumens. If either lumen exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.

21. When adequate aspiration has been achieved, both lumens should be irrigated with saline using quick bolus technique.

22. Close both pinch clamps, remove the syringes, and place a cap on each luer lock hub. Avoid air embolism by keeping extensions tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

Caution: Assure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism.

23. To maintain patency, both lumens should be filled with heparin or heparinized saline. Refer to hospital protocols or guidelines.

CATHETER SECUREMENT AND WOUND DRESSING

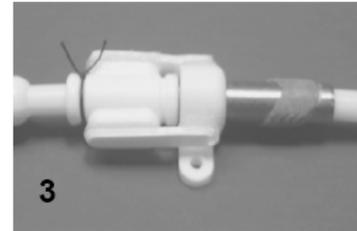
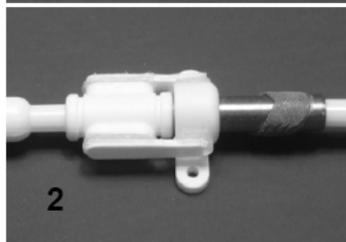
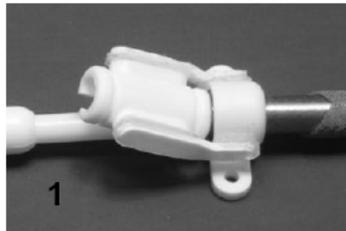
1. Secure the PVAS port to the skin adjacent to the exit site using two sutures to anchor the suture wings to the chest wall.

2. Do not suture the catheter tubing.

Caution: Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

3. Wipe the catheter under the PVAS brake, and flip the PVAS brake over the catheter. Secure the brake to the catheter tubing by tying a single suture around the brake in the proximal groove. The suture should be tied securely. (FIG 1-3).

Caution: Suture should be tight enough to be secure and to prevent the brake from being inadvertently flipped into its unengaged position.



4. Cover the PVAS and catheter exit site using an appropriate dressing. Refer to hospital policies and procedures.
5. The PVAS must remain sutured for at least 6 weeks after implantation.
6. Attach peel-off label to the patient's medical record.
7. If the PVAS or catheter changes position or is inadvertently moved, the position of the catheter tip should be verified by fluoroscopy.

PRECAUTIONS DURING CATHETER USE

1. Examine the PVAS, the catheter, and the extension tubing for possible damage before and after each use.
2. To prevent accidents, insure the security of all caps and bloodline connections prior to and during catheter use.
3. The use of ointments on the catheter surface may cause degradation to the catheter. Do not use ointments on the catheter body.
4. Do not use sharp instruments near the extension tubing or any other part of the catheter.
5. Do use scissors to remove dressing.
6. Use only the pinch clamps that are attached to the extension tubing. The use of any other type of clamp may cause catheter damage and lead to catheter failure.

HEMODIALYSIS TREATMENT

1. Hemodialysis should be performed under a physician's instruction.
2. The heparin locking solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspirate and discard the heparin locking solution before connecting the catheter to the hemodialysis machine.
3. All connections to catheter and extracorporeal circuits should be examined carefully before initiating hemodialysis treatment.
4. Frequent visual inspection of the extracorporeal circuit blood lines should be conducted to detect leaks in order to prevent blood loss or air embolism. If a leak is found, the catheter should be clamped immediately.

Caution: Only clamp catheter with pinch clamps attached to the extension tubes. Do not use any other type of clamping mechanism.

HEPARINIZATION

1. To maintain patency between treatments, a heparin lock should be created in each lumen of the catheter.
2. Follow hospital protocol for anticoagulant lock.
3. Draw heparin into two syringes, corresponding to the amount designated on each catheter lumen. Assure that the syringes are free of air.
4. Verify that both pinch clamps are closed.

5. Remove caps from the luer lock hubs.
6. Secure syringe containing heparin solution to the luer hub of each extension tube.
7. Open extension clamps.
8. Aspirate to insure that no air will be forced into the patient.
9. Inject heparin into each lumen using quick bolus technique.

Note: Each lumen should be completely filled with heparin to insure effectiveness.
10. Close pinch clamps on the extension tubes.

Caution: Pinch clamps should only be open during aspiration, flushing, and hemodialysis treatment.
11. Remove syringes.
12. Attach and secure sterile caps onto the luer hubs.
13. In most instances, no further heparin is necessary for 48-72 hours, provided the catheters have not been aspirated or flushed.

SITE CARE

1. Appropriate site care and catheter care should be determined by hospital policies or guidelines.

WARNING: DO NOT use ointments of any kind with these catheters.
2. Wound dressing must be kept clean and dry.

Caution: Patients must not swim, shower, or soak dressing while bathing.

INFECTION

- Caution:** Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.
- Sterile technique should always be strictly adhered to.
 - Clinical recognized infection at a catheter exit site should be treated promptly with the appropriate therapy

CATHETER EXCHANGE

WARNING: Only a physician familiar with the appropriate techniques should attempt the following procedures.

WARNING: Do not replace a catheter into a tunnel that is suspected to be infected.

1. Prepare the area around the catheter exit site for sterile procedure.
2. Administer sufficient local anesthetic at the exit site and PVAS location to anesthetize completely.
3. Follow hospital protocol for removal of sutures. Cut the single suture from the PVAS brake and flip the brake up and off the catheter.
4. Open the pinch clamp and quickly insert the guidewire down the venous lumen of the dual lumen catheter.
5. Under fluoroscopic observation, advance the guidewire into the inferior vena cava.
6. Apply manual compression to the subcutaneous tunnel to prevent bleeding during the catheter exchange procedure.
7. While securing the PVAS port in position, remove the catheter through the PVAS port, maintaining the position of the guidewire tip.
8. Irrigate inside of the PVAS port with sterile saline to remove debris from interior of the PVAS port.

9. Insert the new replacement catheter over the guidewire. Carefully advance the new catheter through the PVAS port. Continue advancing the catheter over the guidewire into its proper position.
10. If necessary, reposition the catheter tip under fluoroscopic observation.
11. Remove the guidewire.
12. Wipe the catheter under the PVAS brake, and flip the PVAS brake into place over the catheter.
13. Secure the brake to the catheter tubing by tying a single suture around the brake in the proximal groove. The suture should be tied securely but should not be over-tightened. (FIG 1-3).

Caution: The suture should be tight enough to secure and to prevent the brake from being inadvertently flipped into its unengaged position.
14. Do not suture catheter tubing.

Caution: Care must be taken when using sharp objects or needles in close proximity to the catheter lumen. Contact with sharp objects may cause catheter failure.
15. If the catheter is not to be used immediately for treatment, follow the hospital catheter patency guidelines.

CATHETER REPOSITION

- WARNING:** Only a physician familiar with the appropriate techniques should attempt the following procedures.
1. Perform steps 1 through 3 under CATHETER EXCHANGE.
 2. Reposition catheter to restore function. This can be done by rotating the catheter or retracting the catheter proximally (typically less than 2 cm).

WARNING: Do not advance the catheter into the PVAS port to avoid contamination of the tunnel.
 3. After function is restored, confirm the position of the catheter tip.

4. Perform steps 13 through 15 under CATHETER EXCHANGE.

CATHETER REMOVAL

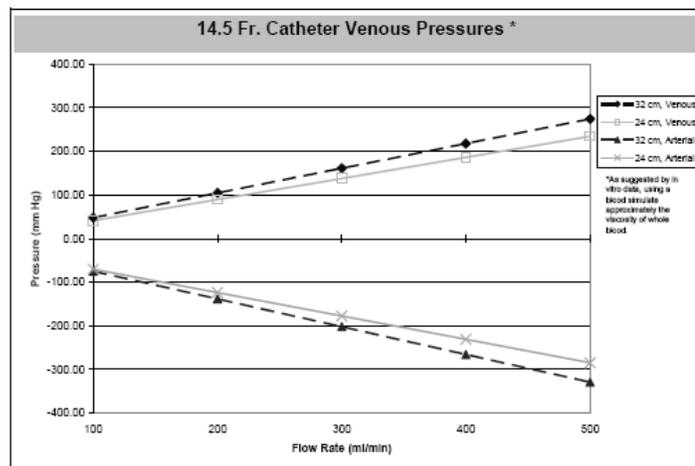
WARNING: Only a physician familiar with the appropriate techniques should attempt the following procedures.

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Palpate the catheter exit tunnel to locate the PVAS port.
2. Administer sufficient local anesthetic to exit site and PVAS location to completely anesthetize.
3. Follow hospital protocol for removal of sutures.
4. Cut the single suture from the PVAS brake and flip the brake up and off the catheter. Apply manual compression to the subcutaneous tunnel to prevent bleeding during catheter removal. While securing the PVAS port in position, remove the catheter through the PVAS port.
5. Cut sutures from PVAS anchor wings.
6. Pull the PVAS brake proximally to evert the PVAS mesh and in-grown tissue.
7. Dissect around the PVAS mesh using blunt and sharp dissection as indicated.
8. Remove the PVAS port through the tunnel.
9. Apply pressure to the proximal tunnel for approximately 10-15 minutes until bleeding stops.
10. Suture the incision and apply dressing in a manner to promote optimal wound healing.

PRIMING VOLUMES:

CATHETER LENGTH	ARTERIAL VOLUME	VENOUS VOLUME
24 cm	1.9 cc	1.9 cc
28 cm	2.0 cc	2.0 cc
32 cm	2.2 cc	2.2 cc



Representative Pouch Label 14.5F Catheter Insertion Kit

DermaPort

TM

PVAS
Ported Vascular Access System
for Hemodialysis and Apheresis
14.5F with Port, 28CM
1 Unit

1 - Catheter with Port and Sheath
1 - 18GA Needle
1 - .038" X 70CM "J" Marked Guidewire
1 - 12F Dilator
1 - 14F Dilator
1 - 16F Grip Lock Sheath with Dilator
1 - Custom Blade
1 - Tunneler with Sleeve
1 - Adhesive Dressing

Single Use Only

YYYY-MM

STERILE EO

MR

USA
Rx
Only

Read
Instructions
for Use

LOT

YYF12345

Contents Sterile and Nonpyrogenic in unopened, undamaged package.
Examine Package for damage.
Rx Caution Federal law restricts this device for sale by or on the order of a physician

DermaPort

PVAS™ for Hemodialysis and Apheresis
MODEL # HD-100-28
1 Unit

400-D10048 Rev F

Made in U.S.A.

Attachment D

510(k) Summary

510(k) Summary

510(k) Sponsor: DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CA 91355

Device Name: PVAS™ Ported Vascular Access System

510(k) Contact: Jennifer Hessel, Director RA/QA
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

Summary Date: June 10, 2009

Trade Name: DermaPort Ported Vascular Access System (PVAS™)

Common Name: Hemodialysis Catheter, Implanted

Classification Name: 21 CFR 876.5540 Blood Access Device and Accessories, Class III,
Product Code: MSD

Predicate Device:
510(k) Number: K071202
Manufacture: DermaPort
Trade Name: Percutaneous Vascular Access System (PVAS)

1.0 Description of Device

The Ported Vascular Access System (PVAS™) has been developed to support central vascular access for hemodialysis and apheresis. This application is for the addition of a 15.5F catheter to the PVAS system and a dilating lead-in to replace the sheath during insertion.

The PVAS port consists of a percutaneous tubular conduit, through which a standard 14.5F or 15.5F polyurethane hemodialysis catheter enters the subcutaneous tunnel. An integral seal surrounds the catheter and prevents microbial migration along the catheter. The PVAS port is enclosed by a silicone anchor that braces the assembly to the skin, and an associated brake holds the catheter in place within the port. A tissue integrating biomaterial surrounds the port, providing anatomical fixation and prevention of microbial migration in a manner analogous to the Dacron cuff of a tunneled catheter.

1.1 Clinical Application

The clinical application of the DermaPort Ported Vascular Access System and catheter is consistent with clinical applications of the predicate DermaPort Percutaneous Vascular Access System cleared to market by 510(k) K071202.

2.0 Intended Use of Device

The indication for use of the PVAS is consistent with the classification of 21 CFR 876.5540 Blood Access Device and Accessories. The indication for use is:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

3.0 Technological Characteristics

The technical characteristics of the Ported Vascular Access System (PVAS™) are the same as the predicate devices in terms of intended use, insertion method, design, materials, performance, labeling, manufacturing process, and method of sterilization. The modifications include: addition of 15.5F catheters incorporation of dilating lead-in, removal of the sheath, replacement of non-valved dilator with a valved dilator, addition of suture to the kit, and replacement of polycarbonate injection caps with ABS injection caps

4.0 Data Summary

The design differences were tested to verify the removal of the sheath, addition of dilating lead-in, change in mesh geometry, 15.5 F catheter and new or modified accessories did not impact the function, performance or safety of the device. The performance testing performed to verify these changes consisted of insertion testing, histopathological analysis of the mesh following implantation in a chronic animal model, biomechanical testing of tissue ingrowth, mesh to port removal force for modified geometry, catheter/port retention testing, microbial ingress and flow versus pressure for new catheter sizes and functional/biocompatibility testing for new accessories. The test methods used to evaluate these changes were equivalent to those applied to the predicate device.

5.0 Conclusions

The modifications to the DermaPort PVAS were evaluated as required by the risk analysis and Design Control requirements. The modified PVAS does not raise new questions of safety or effectiveness.

Attachment E

Indications For Use Form

NOTE: Same as in 510(k) K071202 Indications for Use

510(k) Number (if known): _____

Device Name: DermaPort Ported Vascular Access System (PVAS)

Indications for Use:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Attachment F

Risk Analysis

TABLE 4: Required Actions based on RPN *

Risk Level	Risk Priority Number	Description	Action Required
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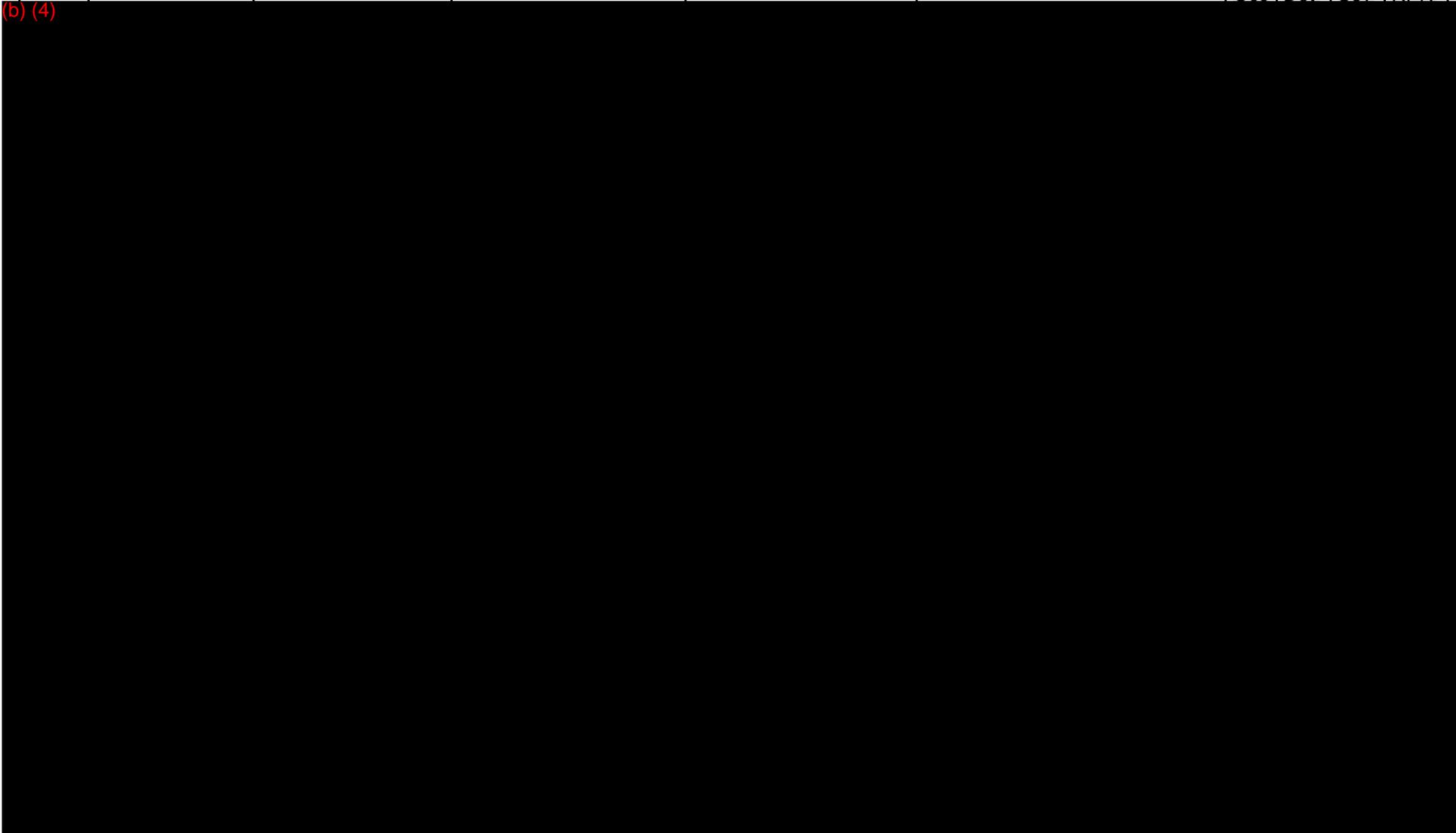
(b) (4)

NOTE: The new risks or risks that are associated with the design change are included in the following Risk Analysis tables for the PVAS. A complete risk analysis for the design is on file at DermaPort

ID#	Function	Potential Failure Mode	Effect	Cause	Mitigation	Evaluation Before Actions			
						Occ	Det	Sev	RPN

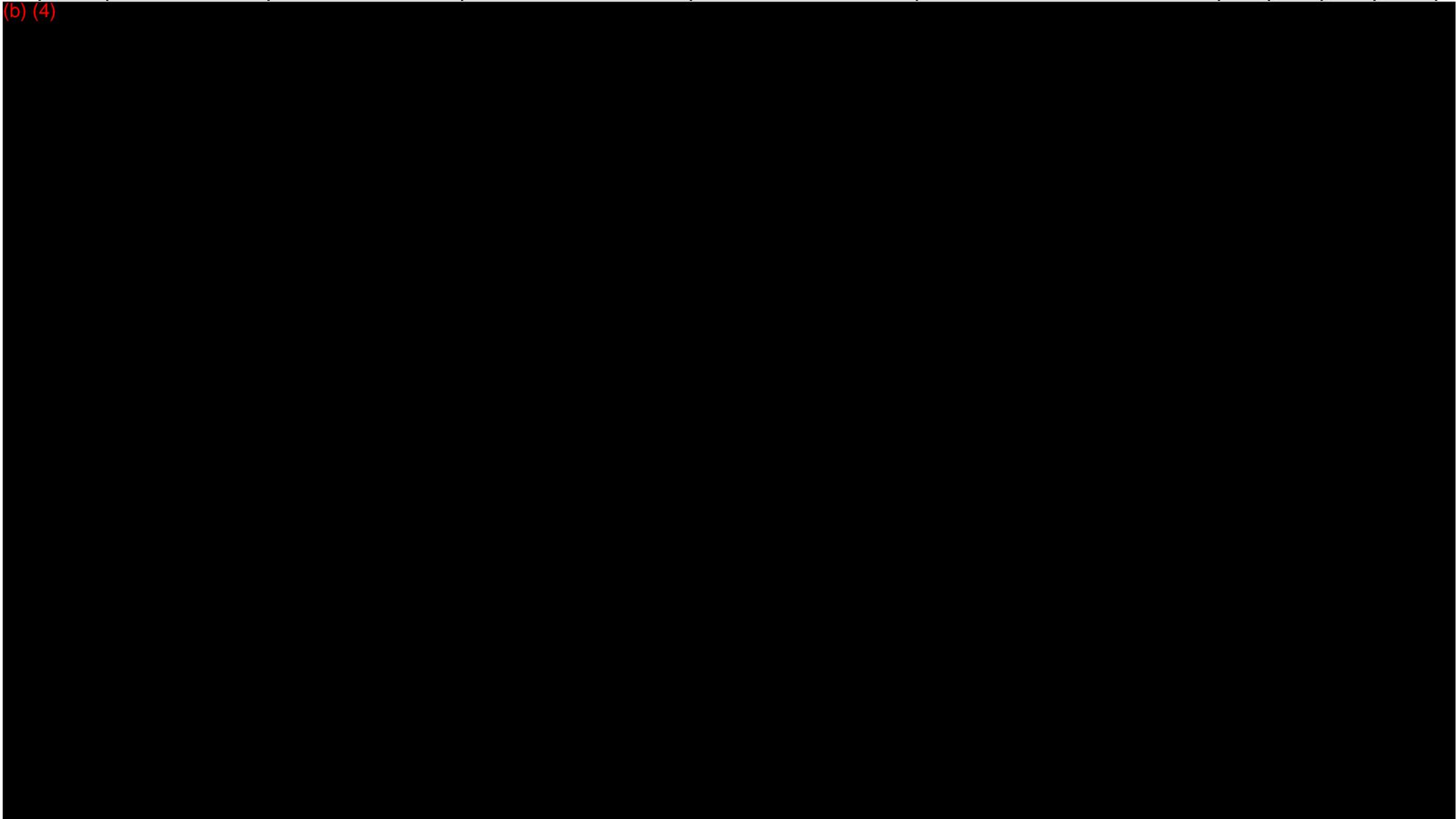
(b) (4)

ID#	Function	Potential Failure Mode	Effect	Cause	Mitigation	Evaluation Before Actions			
						Occ	Det	Sev	RPN



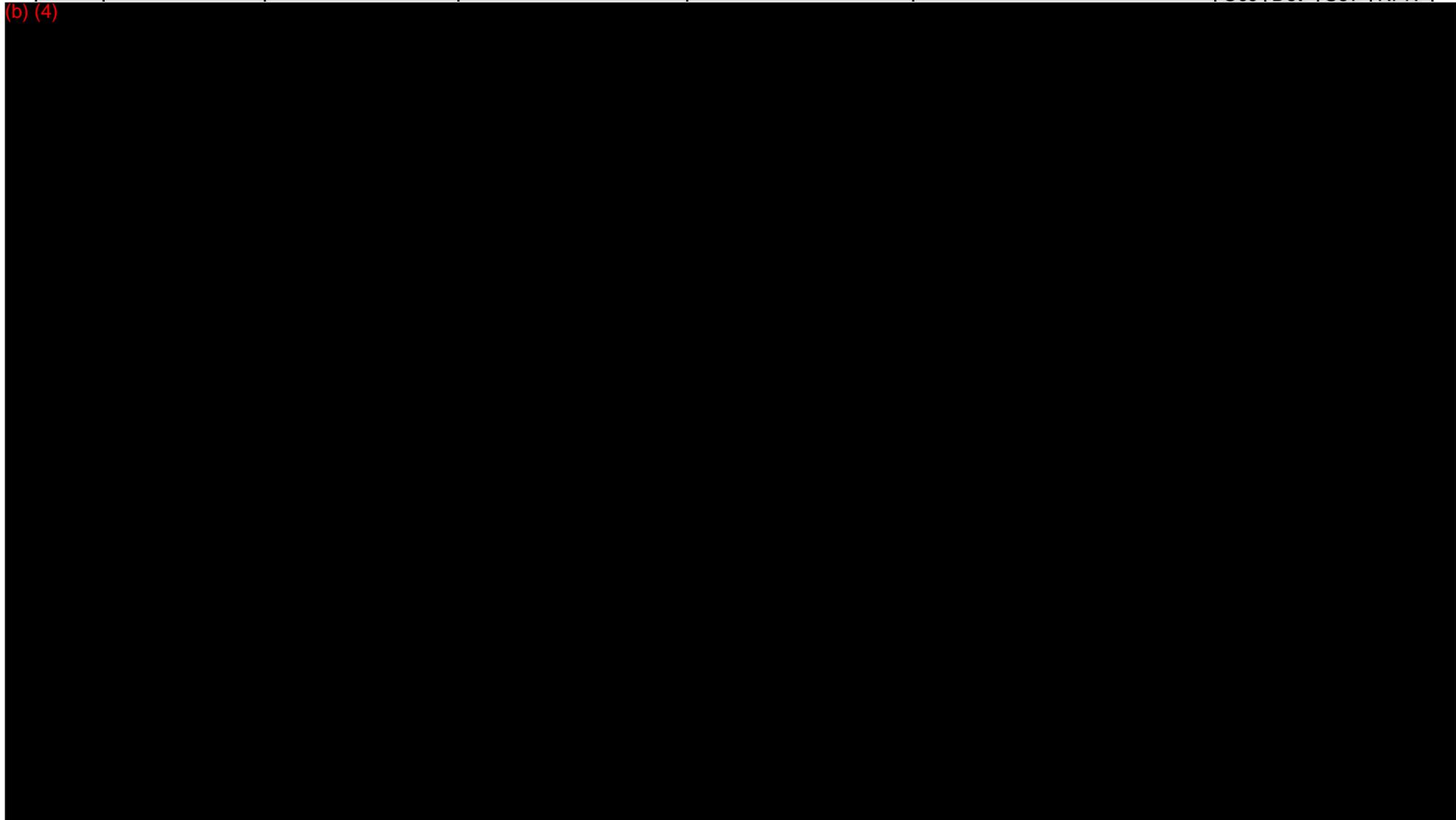
(b) (4)

ID#	Function	Potential Failure Mode	Effect	Cause	Mitigation	Evaluation Before Actions			



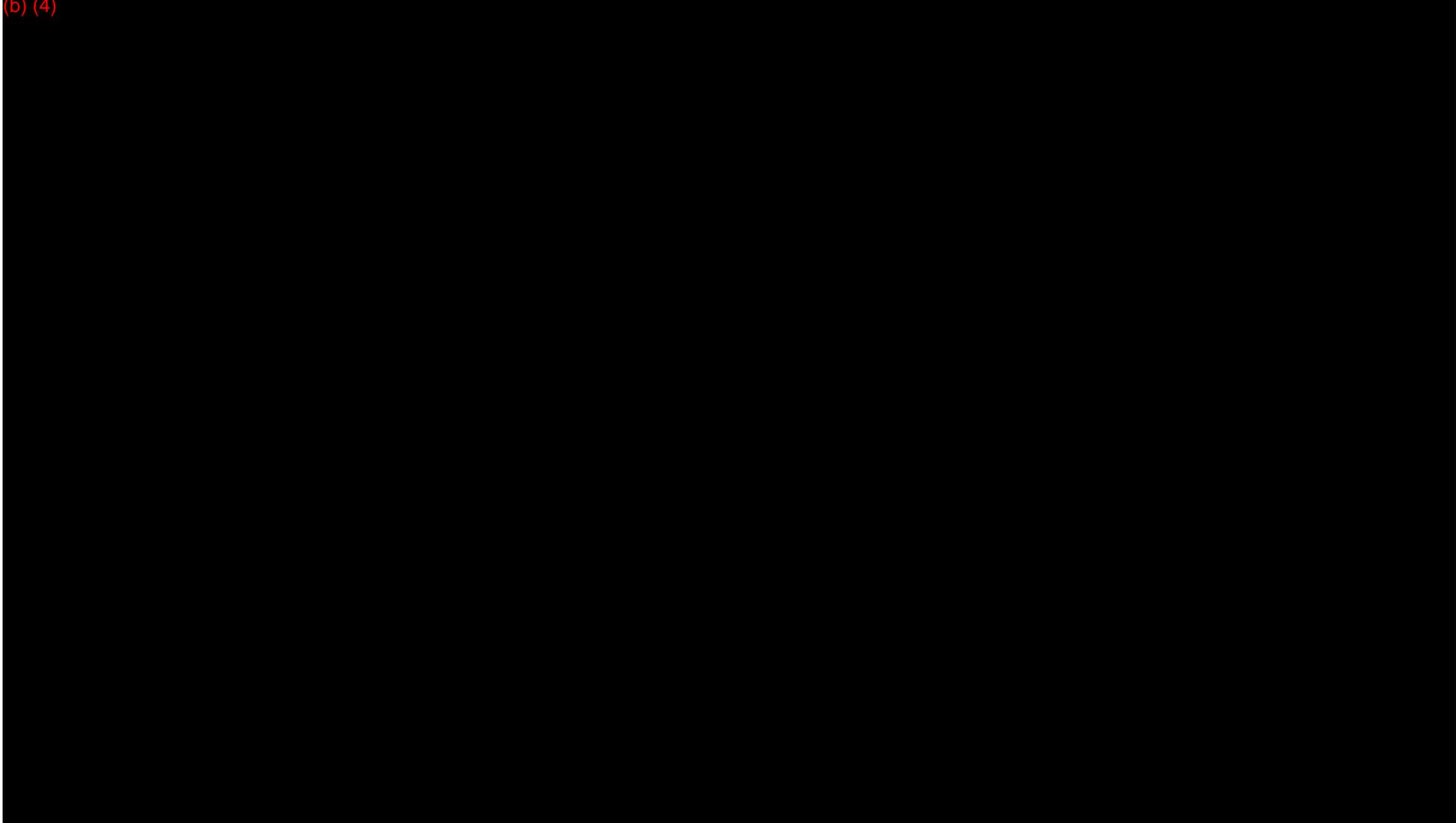
(b) (4)

ID#	Function	Potential Failure Mode	Effect	Cause	Mitigation	Evaluation Before Actions			
						Occ	Det	Sev	RPN



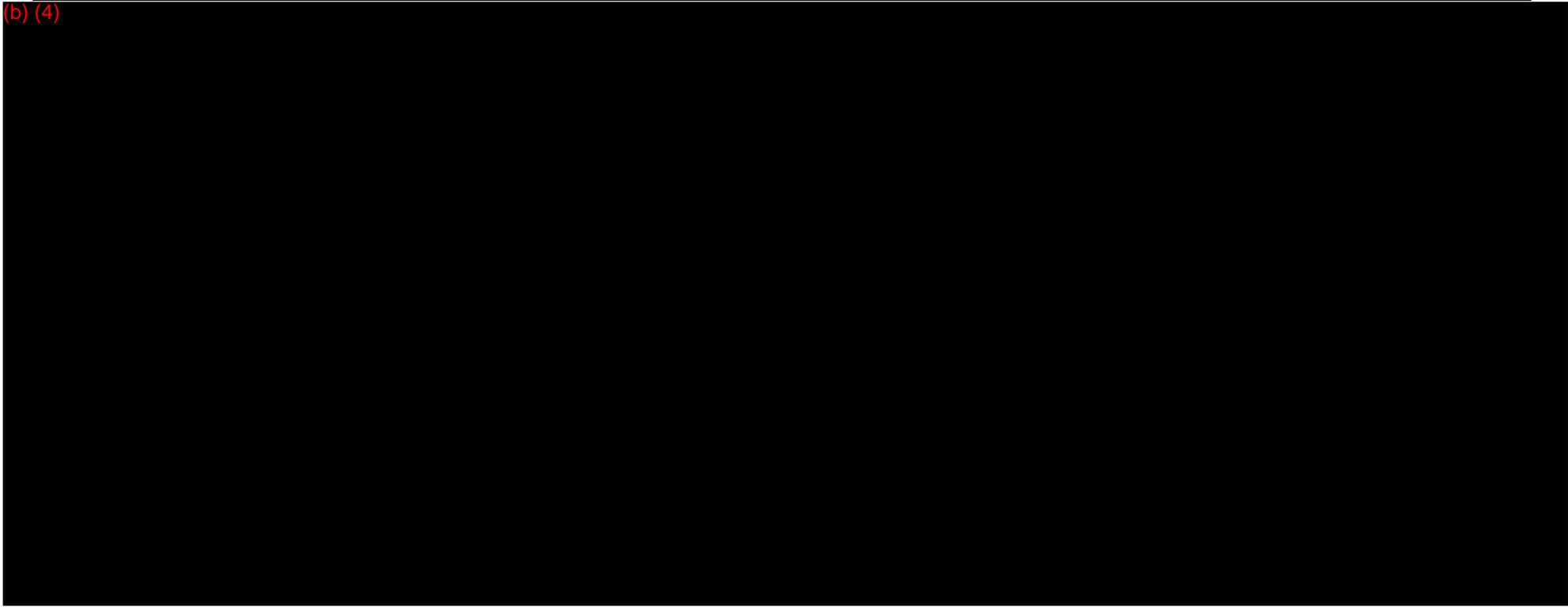
(b) (4)

ID#	Function	Potential Failure Mode	Effect	Cause	Mitigation	Evaluation Before Actions			
						Occ	Det	Sev	RPN



(b) (4)

ID#	Function	Potential Failure Mode	Effect	Cause	Mitigation	Evaluation Before Actions			
						Occ	Det	Sev	RPN



9. OTHER MEDICAL COMPLICATIONS OF HEMODIALYSIS

Risks identified in the Class III Summary of Safety and Effectiveness that are applicable to the PVAS design change are addressed in the Risk Analysis and are included as potential complications in the instructions for use. The Class III Summary is included in **Attachment G**.

Attachment G

Class III Summary and Certification

Class III Summary for the DermaPort Ported Vascular Access System (PVAS)

The types and causes of safety and effectiveness concerns with the DermaPort Ported Vascular Access System (PVAS) device are described in the 510(k) submission reference Section 5: Risk Analysis. A summary of clinical experience to date as well as a summary of complaints received on the PVAS and relevant topics specific to the PVAS design as defined in the risk analysis with regard to safety and effectiveness with these types of devices are included as follows. The design changes were determined to not increase any of these risks and may reduce some of the occurrences.

**PROBLEM WITH EFFICACY,
SAFETY CONCERN, OR
COMPLICATION**

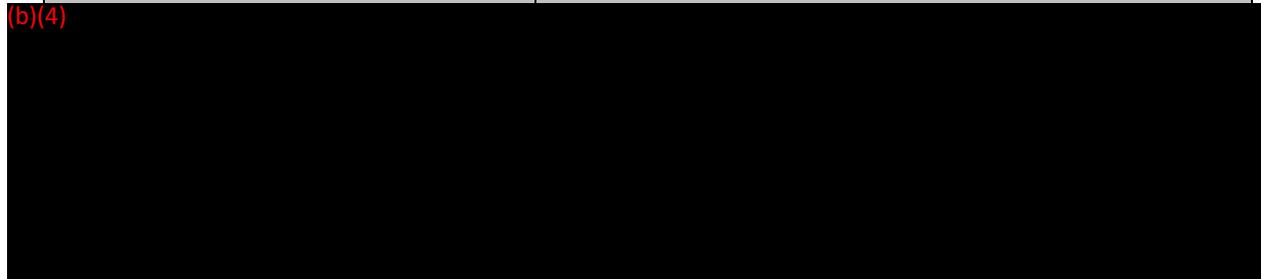
**RESULTS BASED ON CLINICAL USE AND/OR
FROM PRODUCT COMPLAINTS RECIEVED
(Based on use/distribution of approximately 250 PVAS
Insertion and Exchange kits)**

(b)(4)



PROBLEM WITH EFFICACY, SAFETY CONCERN, OR COMPLICATION	RESULTS BASED ON CLINICAL USE AND/OR FROM PRODUCT COMPLAINTS RECEIVED (Based on use/distribution of approximately 250 PVAS Insertion and Exchange kits)
---	---

(b)(4)



None of the PVAS product complaints reported to date have resulted in serious harm to the patient. Several medical interventions were necessary including port and/or catheter replacement or removal, antibiotic administration, pressure dressings, or catheter repairs. These complications and interventions are typical and expected for chronic tunneled hemodialysis catheters.

The literature, including published case reports, clinical trials, meta-analyses, reviews, and clinical practice guidelines for central venous catheters and vascular access was reviewed to identify problems with efficacy, safety concerns and complications. Instructions for Use (IFUs) for currently marketed tunneled central venous catheters were also referenced. In addition, PubMed and MAUDE databases were reviewed. Findings with references are listed in the table below.

PROBLEM WITH EFFICACY, SAFETY CONCERN, OR COMPLICATION	REFERENCES
Air embolism	1, 2, 23, 27, 32, 47-49, 54, 62
Allergic reaction	2, 27, 29
Arterial puncture	1, 54
Arteriovenous fistula	27
Bacteremia	1, 4, 9, 10-12, 14, 15, 17, 19-22, 24, 25, 54, 56-60
Bilateral ophthalmoplegia	38
Bleeding (hemorrhage)	2, 27, 54, 64
Bleeding of esophageal varices	40, 67
Bloodstream infection	28, 41, 42, 60
Brachial plexus injury	1, 2, 23
Cardiac arrhythmia	1, 2, 23, 27, 50

PROBLEM WITH EFFICACY, SAFETY CONCERN, OR COMPLICATION	REFERENCES
Cardiac perforation	23, 27, 50
Cardiac tamponade	1, 2, 23
Catheter colonization	41
Catheter embolism	2, 23
Catheter exchange	55-57, 60
Catheter fragmentation	27, 60, 62
Catheter kinking	14, 26, 27, 31, 60
Catheter misplacement	23, 26, 31, 60
Catheter occlusion, damage or breakage due to compression between the clavicle and first rib	2
Catheter or cuff erosion through skin	2
Catheter or cuff occlusion	2, 23, 26, 27, 60
Catheter port/hub connection failure	27
Catheter related infection	2, 4, 10, 11, 15, 16, 19, 20-24, 26, 27, 29, 30, 31, 43, 44, 46, 53, 57-61
Catheter related sepsis	2, 4, 10, 11, 15, 16, 19, 20-24, 26, 27, 29, 30, 54, 58, 62, 64
Catheter removal	4, 10, 11, 15, 16, 19, 20-24, 26, 27, 29-31, 43, 44, 55, 56
Catheter thrombosis	1, 4, 6, 7, 8, 11-17, 19, 22, 31, 44, 46, 47, 53, 55, 57, 58, 60
Catheter tip migration	27, 31, 46, 50, 60
Cellulitis	59
Central venous thrombosis	1, 11, 13, 19, 23, 31
Chylothorax	23
Contrast reaction	27
Coronary sinus thrombosis	23
Cuff retention	52
Dementia	59
Endocarditis	1, 2, 36
Erosion of port/catheter through skin	27
Exit site infection	1, 2, 10, 12, 14, 15, 17, 20, 21, 24, 29, 30, 41, 54, 58, 60, 64
Exit site necrosis	2

PROBLEM WITH EFFICACY, SAFETY CONCERN, OR COMPLICATION	REFERENCES
Exophthalmos	38
Extravasation	2, 46
Extremity swelling	27
Exsanguination	1, 3
Fibrin sheath formation	2, 11, 27, 31, 53, 55, 57, 60, 61
Hematoma	1, 2, 23, 27, 47, 54, 58
Hemodynamic instability	65
Hemolysis	45
Hemomediastinum	54
Hemopericardium	33
Hemothorax	1, 2, 23, 27, 32, 47, 54
Hepatic vein thrombosis	23
Hydrothorax	2
Inability to access vascular access device	27
Inadvertent catheter removal	27
Infusate infiltration around access device	27
Infusate-related bloodstream infection	29
Intimal injury	27
Intolerance reaction to implanted device	2
Insufficient tissue ingrowth into cuff	3
Laceration of the vessel, or viscus	1, 2, 23, 27, 46, 47
Luminal thrombosis	1, 11, 12, 14, 16
Lymphatic disruption	66
Lymphatic fistula	23
Medastinal injury	1, 23
Meningitis	63
Myocardial erosion	2
Perforation of the vessel or viscus (subclavian vein puncture)	1, 2, 27, 32, 47
Pericatheter bleeding	48
Peripheral neuropathy	59
Persistent hiccups	61

PROBLEM WITH EFFICACY, SAFETY CONCERN, OR COMPLICATION	REFERENCES
Persistent pain at catheter site	27
Phlebitis	29, 41, 46, 47
Phrenic nerve injury	23, 34
Pleural injury	1
Pneumonia	59
Pneumothorax	1, 2, 23, 32, 47, 54
Pocket infection	29, 41, 60
Procedure-induced sepsis	47
Pseudoaneurysm	23, 35
Pulmonary abscess	37
Recirculation	51, 60
Recurrent laryngeal nerve injury	23, 54
Retroperitoneal bleed	1
Right atrial puncture	1
Right atrial thrombus	65
Risks normally associated with local and general anesthesia, surgery, and post-operative recovery	2, 27
Septicemia	1, 10, 15, 19-22, 23, 24, 29, 63
Septic thrombosis	23
Soft tissue swelling	27
Spontaneous catheter tip malposition or retraction	2
Stroke	59
Subcutaneous hematoma	1, 23
Suboptimal blood flow	4, 5, 13, 26, 50, 54, 60
Subcutaneous emphysema	23
Superior vena cava puncture	1
Superior vena cava syndrome	46
Suppurative thrombophlebitis	23
Tension pneumothorax	23
Thoracic duct laceration or injury	1, 2, 23
Thromboembolism	2, 46
Tunnel infection	1, 10, 31, 41, 54, 58, 60, 64

PROBLEM WITH EFFICACY, SAFETY CONCERN, OR COMPLICATION	REFERENCES
Unilateral breast enlargement	39
Vagus nerve injury	23
Vascular thrombosis	1, 2, 4, 6-8, 13, 16, 27, 54, 58
Vasovagal reaction	27
Venous stenosis	4, 7, 8, 13, 15, 16, 18, 27, 39, 53, 54, 64
Ventricular thrombosis	2
Vessel erosion	2, 27,
Wound dehiscence	27, 47

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Class III Certification

DermaPort Ported Vascular Access System (PVAS) with Catheter

I certify, in my capacity as Director of Regulatory Affairs and Quality Assurance of DermaPort, Inc., that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for blood access catheters supporting hemodialysis and apheresis. I further certify that I am aware of the types of problems to which the DermaPort Ported Vascular Access System (PVAS) with Catheter device is susceptible and that, to the best of my knowledge, the summary of the types and causes of safety or effectiveness problems about the DermaPort Ported Vascular Access System (PVAS) type of devices is complete and accurate.

(Signature)

Jennifer Hessel, Director Regulatory Affairs/Quality Assurance
(Printed Name, Title)

(Date)

Attachment H

Standards Data Report Forms for 510(k)

FORM FDA 3654 (9/07)

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(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

ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-199

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 tests?
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: ISO 11607-1 and 11607-2, Packaging for terminally sterilized medical devices

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 and 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.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.4	Select Distribution Cycle	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
DC-13 Motor Freight

DESCRIPTION
Schedule A – Handling, C – Vehicle Stacking, F – Loose-Load Vibration, E – Vehicle Vibration and A - Handling

JUSTIFICATION
Cycle represents expected conditions of distribution and handling for product is expected to undergo

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.

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

11135-1:2007 Sterilization of health care products - Ethylene Oxide Part I

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-228

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 tests?
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 and address of the test laboratory or

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

Sterilization of health care products - Ethylene Oxide Part I Requirements for development, validation and routine control

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Validation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Option selected was Annex B: Conservative determination of lethal rate of the sterilization process - Overkill Approach

DESCRIPTION

The option of utilizing the overkill approach (i.e., half cycles then full) was chosen to validate the EO sterilization cycle

JUSTIFICATION

The overkill approach is an industry standard with the desired acceptance criteria of sterility assurance level (SAL) 10⁻⁶

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

ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-75

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

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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: _____

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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
ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene Oxide Sterilization Residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Categorization of Devices	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Permanent - PVAS Port/Catheter, Prolonged - Dressing, Limited- Accessories (tunneler, dilators, needle, caps, blade)

DESCRIPTION
The categories of device were classified as described above based on duration of product contact

JUSTIFICATION
The PVAS port and catheter is a permanent implant, with dressing having <30 day contact, accessories <24 hours

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4.6	Product Extraction	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Aqueous Extraction

DESCRIPTION
Exhaustive extraction was utilized for permanent contact components, simulated use was utilized for limited exposure type

JUSTIFICATION
The method (exhaustive/simulated use) was chosen per recommendations in the standard based on exposure classification

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

ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and Testing

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-98

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

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Were there any exclusions from the standard?
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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: Compliance with FDA Good Laboratory Practices

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
ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and Testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of Biological Evaluation Tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Nature of Body Contact for Injection Cap

DESCRIPTION
Selected External Communicating Device, Blood Path Indirect, Prolonged Use

JUSTIFICATION
Injection Cap is classified as a blood path indirect based on duration of use and type of body contact

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

DESCRIPTION

JUSTIFICATION

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

DESCRIPTION

JUSTIFICATION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10555-1:1995 Sterile, Single-use Intravascular Catheters – Part 1: General Requirements

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 6-161

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

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Were there any exclusions from the standard?
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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: Guidance on Premarket Notification submission for Short-term and Long-term Intravascular Catheters

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
ISO 10555-1:1995 Sterile, Single-use Intravascular Catheters – Part 1: General Requirements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
[REDACTED]		
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

ISO 10555-3:1996 Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 6-171

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

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Title of guidance: Guidance on Premarket Notification submission for Short-term and Long-term Intravascular Catheters

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SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10555-3:1996 Sterile, Single-use Intravascular Catheters – Part 3: Central Venous Catheters

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER (b) (4)	SECTION TITLE [REDACTED]	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * (b) (4)		
DESCRIPTION (b) (4)		
JUSTIFICATION (b) (4)		

SECTION NUMBER (b) (4)	SECTION TITLE [REDACTED]	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION (b) (4)		
JUSTIFICATION (b) (4)		

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TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-5:1999 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-64

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-5:1999 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		

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† 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.

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

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10:2002 Biological evaluation of medical devices - Part 10: Tests for Irritation and delayed - type hypersensitivity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-87

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 tests?
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: FDA Bluebook Memorandum G95-1

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 and 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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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-10:2002 Biological evaluation of medical devices - Part 10: Tests for Irritation and delayed - type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b) (4)

DESCRIPTION

(b) (4)

JUSTIFICATION

(b) (4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b) (4)

DESCRIPTION

(b) (4)

JUSTIFICATION

(b) (4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b) (4)

DESCRIPTION

(b) (4)

JUSTIFICATION

(b) (4)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for Systemic Toxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-118

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 tests?
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: FDA Bluebook Memorandum G95-1

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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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 and 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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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for Systemic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		
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

ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-199

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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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: ISO 11607-1 and 11607-2, Packaging for terminally sterilized medical devices

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
ASTM D4169:2005, Standard Practice for Performance Testing of Shipping Containers and System

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		

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?
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TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F756-2000: Standard Practice for Assessment of Hemolytic Properties of Materials

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-67

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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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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Were there any exclusions from the standard?
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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: _____

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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
ASTM F756-2000: Standard Practice for Assessment of Hemolytic Properties of Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b) (4)	[REDACTED]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
(b) (4)		
DESCRIPTION		
(b) (4)		
JUSTIFICATION		
(b) (4)		

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COVER SHEET MEMORANDUM

From: Reviewer Name Jeffrey Cooper
Subject: 510(k) Number 1091760/S1
To: The Record

Please list CTS decision code SK

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, 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	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?		✓	
If yes, does firm include Class III Summary?	Must be present for a Final Decision	✓	
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
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)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			N/A
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 ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			N/A
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age <=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

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

510(k) Number: K091760

Section 1: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Missing or Inadequate
Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	√	
Cover Letter Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	√	
Table of Contents	√	
Truthful and Accurate Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_9	√	
Form FDA 3654 - Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf	2	
1: No standard used? = No Standards Form Required		
2: Declaration of Conformity? = Yes Standards Form Required		
3: Standard but no declaration? = Yes Standards Form Required		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	√	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	√	
Proposed Labeling - Device Advice www.fda.gov/cdrh/devadvice/314312.html#link_10	√	
Indications for Use Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_6	√	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	√	
510(k) Summary or 510(k) Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_7	√	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	√	
Identification of legally marketed predicate device. *	√	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	√	
Class III Certification and Summary. **	√	

Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html .		n/a
Kit Certification: Device Advice http://www.fda.gov/cdrh/ode/odecl874.html		n/a

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

** - Required for Class III devices, only.

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

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

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

Passed Screening Yes No - Reviewer: _____
 Concurrence by Review Branch: _____ Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving

these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the A Suggested Approach to Resolving Least Burdensome Issues document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

K091760

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Reviewer: Jeffrey Cooper, D.V.M.

Division/Branch: DRARD/GRDB, HFZ-470

Device Trade Name: Dermaport

510(k) Number: K091760

Common Name: Hemodialysis Catheter

Regulation/Classification: The device is in 21 CFR § 876.5540

Product to Which Compared:

Contact: Jennifer Hessel, Director Regulatory Affairs/Quality Assurance

Company: DermaPort, Inc.

Phone: (661) 362-7904

Fax: (661) 362-7902

Email: jhessel@dermaport.com

	YES	NO	
1. IS PRODUCT A DEVICE?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IF NO STOP
2. DEVICE SUBJECT TO 510(K)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IF NO STOP
3. SAME INDICATION STATEMENT?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	<input type="checkbox"/>	<input type="checkbox"/>	IF YES STOP → NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	<input type="checkbox"/>	<input type="checkbox"/>	IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	IF YES STOP → SE IF NO GO TO 10
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	<input type="checkbox"/>	<input type="checkbox"/>	IF YES STOP → NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?	<input type="checkbox"/>	<input type="checkbox"/>	IF NO STOP → NE
10. PERFORMANCE DATA AVAILABLE?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	IF YES STOP → SE

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

Explanations to the Preceding Checklist:

7. Biocompatibility:

11. The test results are acceptable.

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: See Below.

2. DEVICE DESCRIPTION: See Below.

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE

RE: K091760 - Dermaport, Inc. – Dermaport Ported Vascular Access System (PVAS) for Long-Term Hemodialysis

Jennifer Hessel, Director Regulatory Affairs/Quality Assurance
DermaPort, Inc.
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

DermaPort Percutaneous Vascular Access System (PVAS™) K071202

2. Submitter's statement that the indication/ 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.

These are present and are acceptable:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

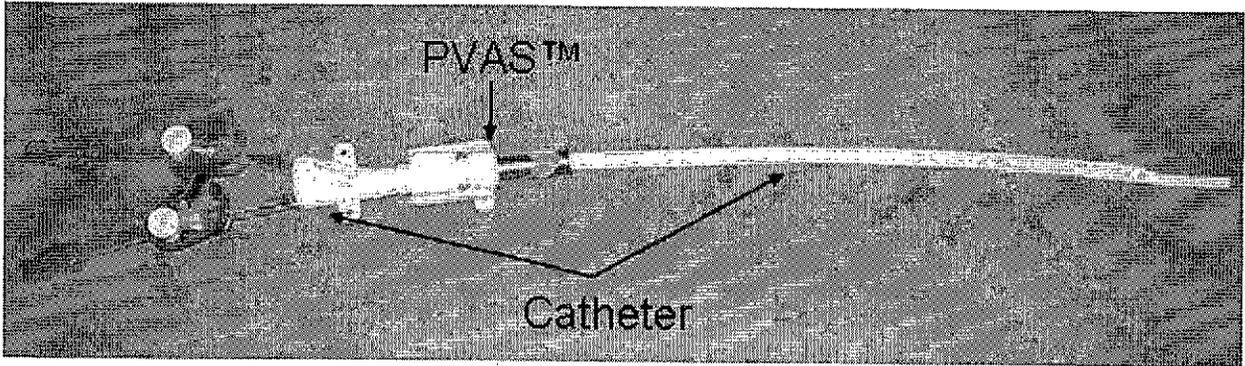
Predicate:

The DermaPort Percutaneous Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and the catheter is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

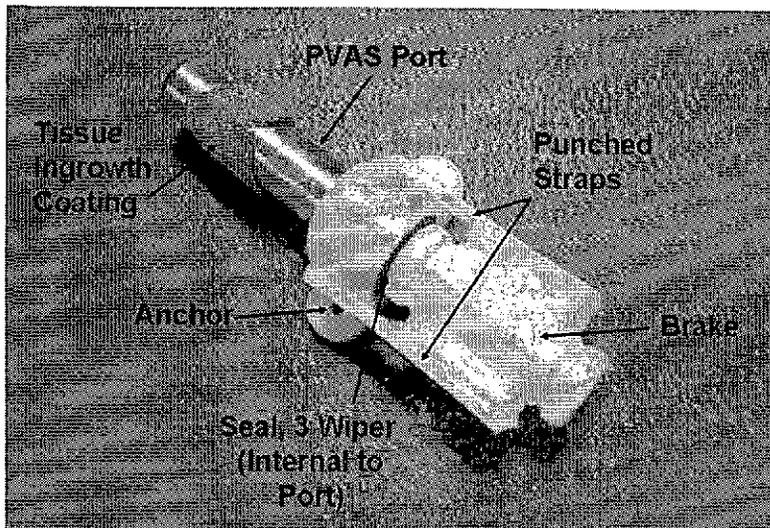
3. A description of the device modifications including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the fundamental scientific technology of the modified device has not changed.

This was provided.

The DermaPort Ported Vascular Access System (PVAS) was designed to facilitate hemodialysis catheter placement, repositioning, and exchange procedures while maintaining catheter attachment, epidermal barrier and fixation functions.



The PVAS port consists of a percutaneous tubular conduit, through which a standard polyurethane hemodialysis catheter enters the subcutaneous tunnel providing access to the central venous system. An integral three (3) wiper seal surrounds the catheter at the interface with the port and resists microbial migration along the catheter. The port is enclosed by a silicone anchor that secures it to the skin, and an associated brake holds the catheter in position to the port.



Summary of Modifications

(1) The modified PVAS includes the addition of (b) (4)

(b) (4) to add to the already cleared 24, 28 and 32 cm lengths. (b) (4) catheter is manufactured utilizing the same materials and manufacturing process as the 14.5F DermaPort dual lumen polyurethane catheter with the exception that the outside diameter increased from (b) (4)

(2) In order to accommodate the (b) (4) catheter the inside diameter of the port was increased from (b) (4) (b) (4) larger diameter catheter. The diameter of the port where the internal three wiper seal is bonded was not modified. The internal three wiper seal serves as a physical barrier to minimize bacterial contamination of the subcutaneous tunnel during subsequent catheter repositioning or exchange procedures.

(3) The PVAS peel-away dilating sheath was removed and replaced with a dilating lead-in integrated into the titanium PVAS port. During the current PVAS insertion procedure, the peel-away sheath eases insertion while protecting the incision site. The proposed change is the replacement of the sheath component covering the PVAS during insertion with a dilating lead-in port housing; this simplifies the

insertion procedure for the user. The tissue ingrowth coating (mesh) will still be protected during shipping and handling by a new protective cover made from the same material as the current sheath.

(4) The mesh configuration on the port was changed from (b) (4) (b) (4) material that promotes tissue ingrowth and fixation of the device is attached to the metal surface of the PVAS port. This change was made for ease in manufacturing as it allows for the lead-in to be simplified in not having to conform to the diagonal shape of the mesh.

(5) In order to differentiate between the predicate PVAS port that is only able to accept 14.5F catheters and the modified design which can accommodate both the 14.5F and (b) (4) catheters, the modified configuration is denoted by an embossed symbol on the silicone anchor. A picture has been included in the Instructions for Use under Catheter Exchange section, along with the following warning statement: "WARNING: A PVAS port which can accommodate both a 14.5 and (b) (4) 14.5F (b) (4) symbol on the anchor. Use a (b) (4) catheter only in ports labeled with the symbol as seen below."

(6) Addition or changes to the following accessories in the PVAS kit have been made:

(b) (4)

The following changes were made to the PVAS since the original 510(k) submission and were controlled under the design control system:

(b) (4)

(7) Modification to Instructions for Use for clarification of suture use, the following changes were made:

(b) (4)

(b) (4)

- 4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device include labeling, intended use, physical characteristics, and materials.

(b) (4)

Intended use: Same.

Sterility: Yes - same

(b) (4)

Table 7.1.1-1: Regulatory Status of Components				
Description	Supplier	Supplier Part	FDA Regulatory Basis	FDA Class

(b) (4)

Testing:

(b) (4)

- 5. A Design Control Activities Summary which includes:

(b) (4)

(b) (4)

These are signed.

6. A Truthful and Accurate Statement, a 510(k) Summary, and the Indications for Use Enclosure.

These are enclosed.

Consults:

None

Questions:

1. Please provide a signed kit certificate for the change to the FlowGuard® 16F Valved Peelable Introducer. The certificate should include all of the kit components.

This is now provided and complete.

2. The FDA checklist requests that the "Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis" should be stated. Please state the risk analysis method that you used.

(b) (4)

3. You provided the following Design Control Compliance Certification:

(b) (4)

The FDA checklist requests "A Declaration of Conformity with design controls that includes the following statements:

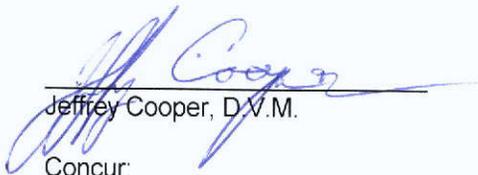
- a. A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met? This statement is signed by the individual responsible for those particular activities; and
- b. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.

Please provide the signed statements requested in a. and b.

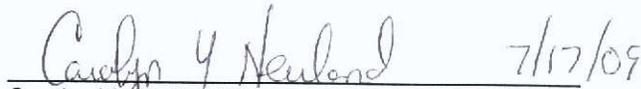
These are provided.

Recommendation:

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, the firm claims the device to be substantially equivalent to the previously cleared device.


Jeffrey Cooper, D.V.M.
Concur:

7/15/09
Date


Carolyn Y. Neuland, Ph. D.
Chief, Gastroenterology and Renal Devices Branch



COVER SHEET MEMORANDUM

From: Reviewer Name Jeffrey Cooper
 Subject: 510(k) Number K091760
 To: The Record

- Please list CTS decision code _____
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, 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		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO_MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
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 ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age ≤ 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Cooper, Jeffrey (CDRH)

From: Cooper, Jeffrey (CDRH)
Sent: Thursday, July 09, 2009 4:02 PM
To: 'jhessel@dermaport.com'
Subject: K091760

I am reviewing your submission and have the following deficiencies. I am placing your submission on telephone hold while waiting for your responses by email and by paper to the document mail center.

1. Please provide a signed kit certificate for the change to the FlowGuard® 16F Valved Peelable Introducer. The certificate should include all of the kit components.
2. The FDA checklist requests that the "Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis" should be stated. Please state the risk analysis method that you used.
3. You provided the following Design Control Compliance Certification:

"I certify that in my capacity as Director of Regulatory Affairs and Quality Assurance, the modified Ported Vascular Access System (PVAS™) verification and validation complies with the DermaPort design control process. The DermaPort design control process is in compliance with the requirements specified in 21 CFR 820.30. All risks resulting from the described modifications were mitigated, designated individuals implemented verification and validation activities. The results demonstrate the predetermined acceptance criteria are met." This statement partially combines the statements request in FDA's checklist.

The FDA checklist requests "A Declaration of Conformity with design controls that includes the following statements:

- a. A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities; and
- b. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.

Please provide the signed statements requested in a. and b.

Thank you,

Jeffrey Cooper, M.S., D.V.M.

Veterinary Medical Officer

Center for Devices & Radiological Health (CDRH)

Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal and Radiological Devices (DRARD)

Gastroenterology and Renal Devices Branch (GRDB)

9200 Corporate Boulevard HFZ-470

7/9/2009

28

Rockville, MD 20850
(240) 276-4132
jeffrey.cooper@fda.hhs.gov

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE

RE: K091760 - Dermaport, Inc. – Dermaport Ported Vascular Access System (PVAS) for Long-Term Hemodialysis

Jennifer Hessel, Director Regulatory Affairs/Quality Assurance
DermaPort, Inc.
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

DermaPort Percutaneous Vascular Access System (PVAS™) K071202

2. Submitter's statement that the indication/ 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.

These are present and are acceptable:

The DermaPort Ported Vascular Access System (PVAS™)
is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

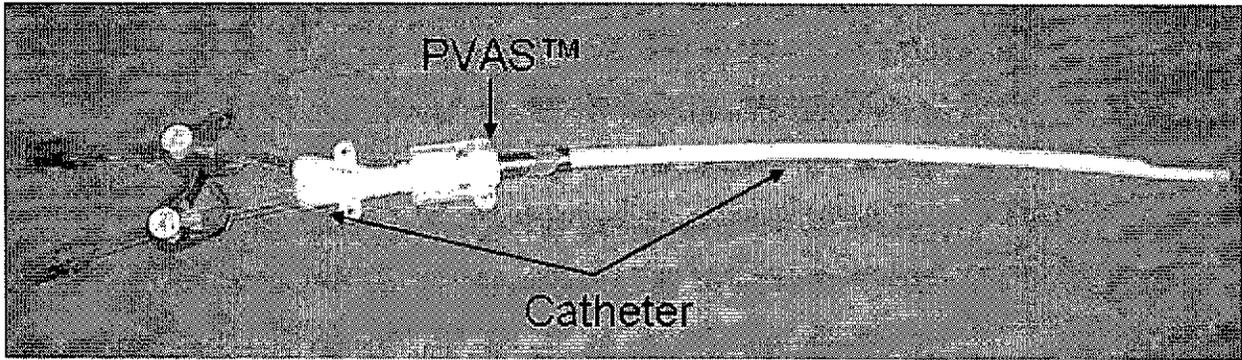
Predicate:

The DermaPort Percutaneous Vascular Access System (PVAS™)
is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and the catheter is typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

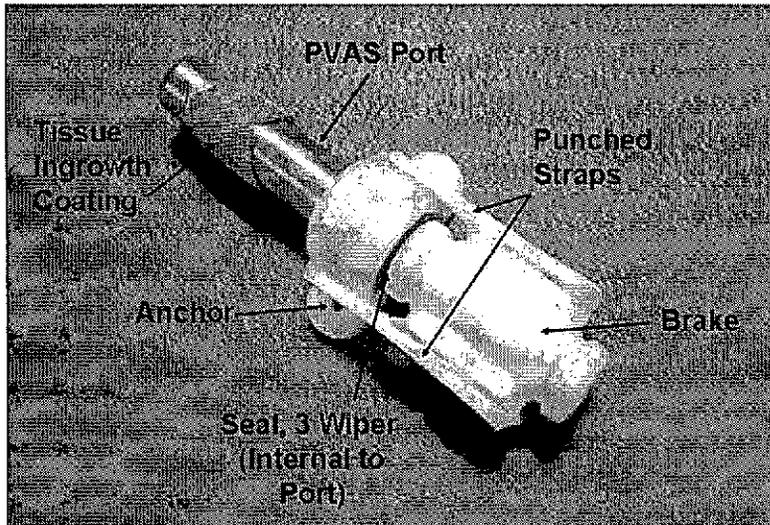
3. A description of the device modifications including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the fundamental scientific technology of the modified device has not changed.

This was provided.

The DermaPort Ported Vascular Access System (PVAS) was designed to facilitate hemodialysis catheter placement, repositioning, and exchange procedures while maintaining catheter attachment, epidermal barrier and fixation functions.



The PVAS port consists of a percutaneous tubular conduit, through which a standard polyurethane hemodialysis catheter enters the subcutaneous tunnel providing access to the central venous system. An integral three (3) wiper seal surrounds the catheter at the interface with the port and resists microbial migration along the catheter. The port is enclosed by a silicone anchor that secures it to the skin, and an associated brake holds the catheter in position to the port.



Summary of Modifications

(1) The modified PVAS includes the addition of (b) (4) catheters of (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(4) The mesh configuration on the port was changed from (b) (4) A section of porous, tissue-integrating (b) (4) material that promotes tissue ingrowth and fixation of the device is attached to the metal surface of the PVAS port. This change was made for ease in manufacturing as it allows for the lead-in to be simplified in not having to conform to the (b) (4) of the mesh.

(5) In order to differentiate between the predicate PVAS port that is only able to accept 14.5F catheters and the modified design which can accommodate both the 14.5F and (b) (4)

(6) Addition or changes to the following accessories in the PVAS kit have been made:

(b) (4)

The following changes were made to the PVAS since the original 510(k) submission and were controlled under the design control system:

(b) (4)

(7) Modification to Instructions for Use for clarification of suture use, the following changes were made:

(b) (4)

(b) (4)

- 4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device include labeling, intended use, physical characteristics, and materials.

(b) (4)

Intended use: Same.

Sterility: Yes - same

Biocompatibility: The caps had all 5 tests done; Cytotoxicity, sensitization, intracutaneous reactivity, acute toxicity, and hemolysis. For the markings, the ink is the same as on other catheters manufactured by

(b) (4)

Table 7.1.1-1: Regulatory Status of Components				
Description	Supplier	Supplier Part Number	FDA Regulatory Basis	FDA Class

(b) (4)

Testing:

(b) (4)

- 5. A Design Control Activities Summary which includes:

- a) Identification of Risk Analysis method used to assess the impact of the modification on the device and its components, and the results of the analysis:

Not Stated

- 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

Testing was done to design control criteria. This is acceptable.

- c) A declaration of conformity with design controls. The declaration of conformity includes:

- 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.

These are merged into one paragraph. These need to be re-done.

- 6. A Truthful and Accurate Statement, a 510(k) Summary, and the Indications for Use Enclosure.

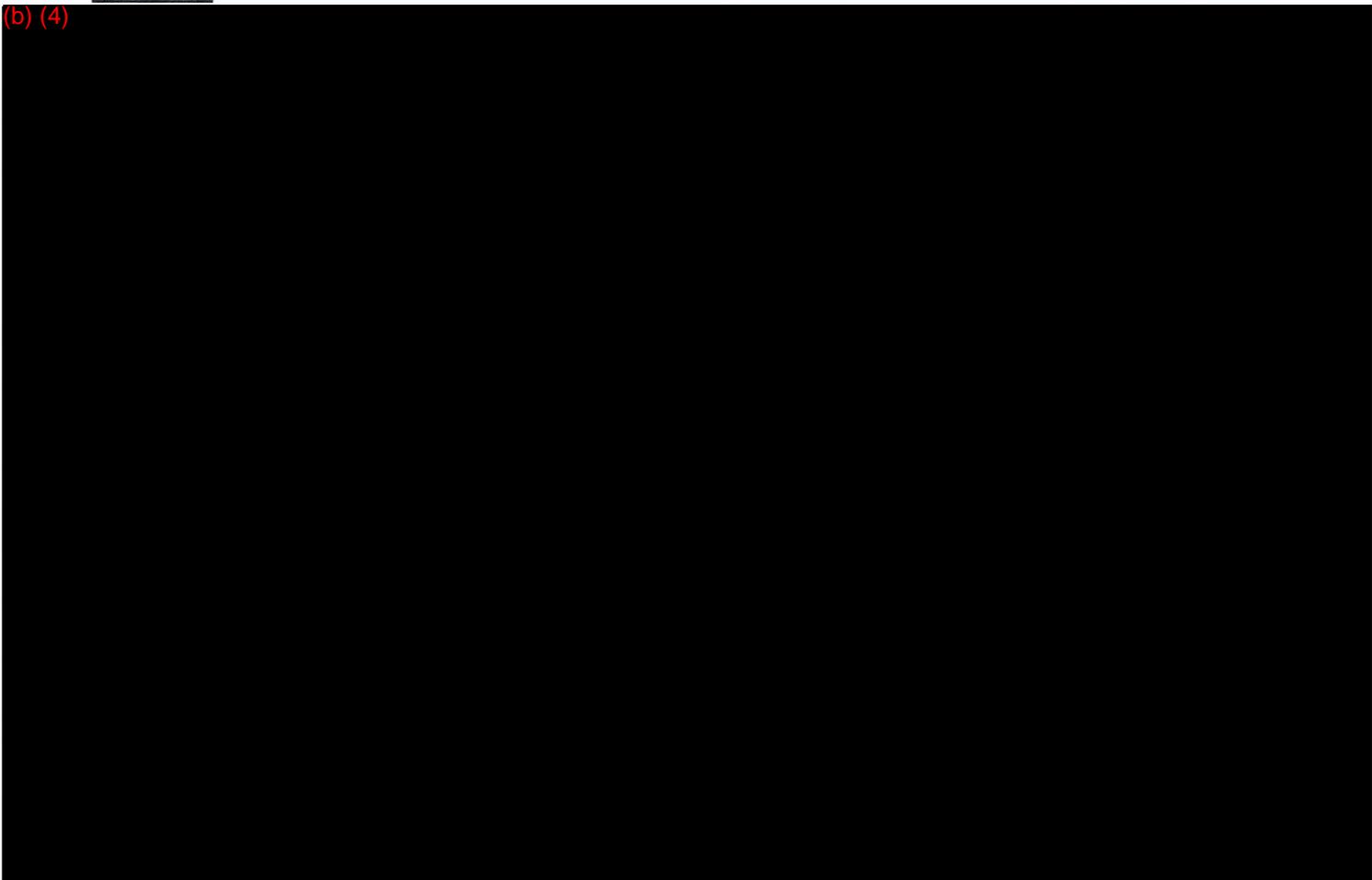
These are enclosed.

Consults:

None

Questions:

(b) (4)



Recommendation:

Telephone hold.



Jeffrey Cooper, D.V.M.



Date

Concur:

Carole A. Part for Neuland

Carolyn Y. Neuland, Ph. D.
Chief, Gastroenterology and Renal Devices Branch

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

510(k) Number: K091760

Section 1: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Missing or Inadequate
Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	√	
Cover Letter Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	√	
Table of Contents	√	
Truthful and Accurate Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_9	√	
Form FDA 3654 - Standards Data Report for 510(k)s – http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf	2	
1: No standard used? = No Standards Form Required		
2: Declaration of Conformity? = Yes Standards Form Required		
3: Standard but no declaration? = Yes Standards Form Required		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	√	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	√	
Proposed Labeling - Device Advice www.fda.gov/cdrh/devadvice/314312.html#link_10	√	
Indications for Use Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_6	√	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	√	
510(k) Summary or 510(k) Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_7	√	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	√	
Identification of legally marketed predicate device. *	√	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	√	
Class III Certification and Summary. **	√	

Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html .		n/a
Kit Certification: Device Advice http://www.fda.gov/cdrh/ode/odecl874.html		n/a

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

** - Required for Class III devices, only.

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

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

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

Passed Screening Yes No - Reviewer: _____
 Concurrence by Review Branch: LED for ED Date: 7/9/09

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving

these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the A Suggested Approach to Resolving Least Burdensome Issues document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>



July 15, 2009

DERMAPORT, INC
25102 RYE CANYON LOOP SUITE 110
SANTA CLARITA, CALIFORNIA 91355
UNITED STATES
ATTN: JENNIFER HESSEL

510k Number: K091760

Product: DERMAPORT PORTED VASCULAR

The additional information you have submitted has been received.

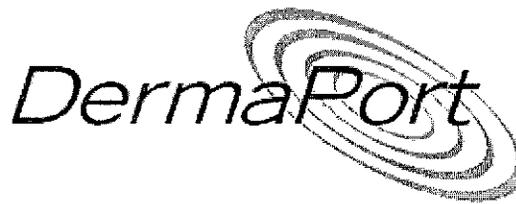
We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k 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



K091760/S1

July 13, 2009

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

FDA CDRH DMC
JUL 15 2009
Received

Re: 510(k) K091760 DermaPort Ported Vascular Access System (PVAS™),

We are writing in reply to the deficiency notification email dated July 9th, 2009 requesting clarification pertaining to the 510(k) K091760, *DermaPort Ported Vascular Access System (PVAS™)*. In response to the deficiencies noted:

1. *Please provide a signed kit certificate for the change to the FlowGuard® 16F Valved Peelable Introducer. The certificate should include all of the kit components.*

RESPONSE: As requested a Kit certification is included as an attachment.

2. *The FDA checklist requests that the "Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis" should be stated. Please state the risk analysis method that you used.*

RESPONSE: Failure Modes and Effects Analysis methodology was used to perform the risk analysis to assess the modifications to the DermaPort Ported Vascular Access System (PVAS). DermaPort's Risk Analysis process is compliant with the Quality System Regulation (QSR) and ISO 14971:2007 - Medical devices — Application of risk management to medical devices. The risks of the PVAS are mitigated to acceptable levels by application of labeling, selection of materials, controlled manufacturing processes, specification and verification. All resulting mitigated risks are found to be acceptable.

102519

3. The FDA checklist requests "A Declaration of Conformity with design controls that includes the following statements:
- a. A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities; and
 - b. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.

Please provide the signed statements requested in a. and b

RESPONSE: As requested a revised Declaration of Conformity with Design Controls is included as an attachment to this response.

We believe the responses answer the questions asked and support a conclusion of substantial equivalence. Please contact me with any questions.

Regards,



Jennifer Hessel
Director, Regulatory Affairs and Quality Assurance
DermaPort, Inc.
Phone: (661) 362-7904
Fax: (661) 362-7902
Email: jhessel@dermaport.com

Attachment A: Kit Certification

As described, the PVAS is a kit. The kit components include Class III and Class I FDA regulated components. Table 1.0 defines the FDA regulatory basis for the kit components that are currently cleared to market devices. The only added kit component from the predicate 510(k) addressed in this 510(k) is the 16F FlowGuard® Peelable Introducer and Injection Cap.

Description	Supplier	Supplier Part #	FDA Regulatory Basis	FDA Class
Implanted Hemodialysis Catheter with Markings	(b) (4)	(b) (4)	K091760	
Guidewire 70 cm			K770977 (Cardiovascular Spring Guides)	II
Guidewire 100 cm			K770977 (Cardiovascular Spring Guides)	II
16F FlowGuard® Peelable Introducer			K040150 (FlowGuard Peelable Introducer)	II
12F, 14F Polyethylene Dilator			K040318 (SPLIT CATH III)	III
Clear Female Dust Cover			K040318 (SPLIT CATH III)	III
Injection Cap			K091760	
18 GA x 2.7" Cryolite Introducer Needle			K040318 (SPLIT CATH III)	III
Tunneler with Tri ball tip			K994105 (Hemoflow)	III
Tunneler Sleeve			K994105 (Hemoflow) & K020465 (SPLIT CATH II)	III
DermaPort Blade			878.4800 Manual surgical instrument for general use; 510(k) exempt	I
Suture			K001434 ('cottony' II)	II

DermaPort applied processes to these components is consistent with the predicate 510(k). The processes of packaging, sterilization and labeling are applied. All of the noted components are used for the indication for use cleared to market by the noted 510(k) or are 510(k) exempt in compliance with the noted regulation. The following Kit Certification is provided to support the FDA regulation status of all components.



Kit Certification

DermaPort Ported Vascular Access System (PVAS)

I certify that the components of the DermaPort Ported Vascular Access System (PVAS) kit are either:

- (1) legally marketed pre-Amendments devices,
- (2) exempt from premarket notification consistent with the exemption criteria described in the classification regulation(s) and the limitation of exemptions for Section 510(k) of the act (e.g., 878.9), or
- (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).

I further certify that these components are consistent with their pre-Amendments, exemption, or premarket notification criteria and status.



(Signature)

Jennifer Hessel, Director RA/QA

(Printed Name, Title)

13 July 2009

Date



Declaration of Conformity

DermaPort Ported Vascular Access System (PVAS) with Catheter

Compliance to Design Controls

I certify that in my capacity as Director of Regulatory Affairs and Quality Assurance, the DermaPort design control process for the modified Ported Vascular Access System (PVAS™) as required by risk analysis, all verification and validation were performed by the designated individuals and the results of the activities demonstrated that the predetermined acceptance criteria were met.

The DermaPort manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

A handwritten signature in blue ink, appearing to read "J. Hessel", is written over a horizontal line.

(Signature)

Jennifer Hessel, Director RA/QA

(Printed Name, Title)

13 July 2009

Date