SECTION 5.0

510(k) Summary

SUBMITTER:
R4 Vascular, Inc.
7550 Meridian Circle
Suite 150
Maple Grove, MN 55369

ESTABLISHMENT REGISTRATION NUMBER:
3006242715

CONTACT:
Laurie Lewandowski
Director, Quality and Regulatory Affairs
Telephone: 612-770-4038 cell
Telephone: 763-494-8400
Fax: 763-494-8484
Email: **lalew@r4vascular.com**

DATE PREPARED:
December 16, 2008

NAME OF MEDICAL DEVICE:

Proprietary Name:	***Zeus™ CT PICC***
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC), single and double lumen

DEVICE CLASSIFICATION:

Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	LJS
Regulation Number:	21 CFR 880.5970

PREDICATE DEVICES:

Proprietary Name:	V-Cath (Polyurethane) Power PICC (Power-V)
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC), single and double lumen

Proprietary Name:	Tyco Palindrome Emerald
Regulation Name:	Chronic Hemodialysis Catheter
Common/Usual Name:	Catheter, Hemodialysis, Apheresis, Intravascular

Device Description:

The r4 Vascular, Inc. *Zeus™ CT PICC* is a family of peripherally inserted central venous catheters designed to perform infusion, intravenous therapy, blood sampling, power injection of contrast media studies and central venous pressure monitoring. The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each *Zeus™ CT PICC* has a kink resistant reverse tapered catheter design. The *Zeus™ CT PICC* kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The *Zeus™ CT PICC* product line has catheters in 4 Fr and 5 Fr single lumen and 5 Fr and 6 Fr dual lumen.

The *Zeus™ CT PICC* is similar to HDC's V-Cath (Polyurethane) Power PICC (Power-V), with the addition of a Biomimetic Coating that is similar in performance to the Tyco Palindrome Emerald.

Intended Use / Indication for Use:

The Zeus ™ *CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

Technological Comparison to Predicate Devices:

The technological characteristics of the *Zeus™ CT PICC* are substantially equivalent to the predicates, HDC's V-Cath (Polyurethane) Power PICC (Power-V) and Tyco Palindrome Emerald in terms of intended use, application, user population, basic design, performance and labeling.

New device is compared to Marketed Device? Yes. It is compared to legally marketed predicates.

Does the new device have the same indication statements? Yes.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Not in all regards. The principles of operations and basic design are the same as the predicate devices. The main change in design is the addition of the biomimetic coating to the catheter.

There is precedence in the market for coated catheters, Tyco Palindrome Emerald and their predicates.

Could the new characteristics affect safety or effectiveness? Yes. The changes may affect safety and effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

Yes. Testing was based on FDA guidance documents and recognized standards to evaluate the devices' performance.

- The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95 was used to determine the appropriate methods for evaluating the device's performance.
- ISO 10555-1:1997 Sterile, Single-use Intravascular Catheters, General requirements;
- ISO 594 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment-Part1: General requirements
- AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 10993 Biological Evaluation of Medical Devices Part-1: Evaluation and Testing

Sterilization requirements of ISO 11135:2007, *Sterilization of Health Care Products - Requirements for Validation and Routine Control -- Ethylene Oxide Sterilization.*

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.* Test profiles for externally communicating, blood-contacting, long-term devices will be met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Performance testing was generated in accordance with the above referenced guidance document and standards.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrate that the *Zeus™ CT PICC* with biomimetic coating met the performance criteria of safety and effectiveness test performed and based on the FDA's decision tree is substantially equivalent to the noted predicate devices.

CONCLUSION

The *Zeus*™ *CT PICC* met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the *Zeus*™ *CT PICC* is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate devices: HDC V-Cath (Polyurethane) Power PICC (Power-V) and Tyco Palindrome Emerald.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2009

Ms. Laurie Lewandowski
Director, Quality and Regulatory Affairs
R4 Vascular, Incorporated
7550 Meridian Circle North
Suite 150
Maple Grove, Minnesota 55369

Re: K083763
Trade/Device Name: Zeus CT PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 16, 2008
Received: December 18, 2008

Dear Ms. Lewandowski:

This letter corrects our substantially equivalent letter of March 16, 2009.

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

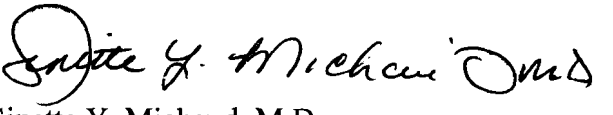
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0

Indications for Use

510(k) Number (if known): K083763

Device Name: Zeus CT PICC

Indications For Use:

The *Zeus™ CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommednded infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083763