510(K) SUMMARY

K042566

NOV - 8 2004

Submitter's Name

Vasc-Alert L.L.C.
1807 W. Sunnyside Ave. Suite 301
Chicago, IL 60640

Contact Person

John Kennedy, President
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Date of preparation of this summary: September 15, 2004

General Information

Proprietary Name	Vasc-Alert: Vascular Data Analysis for Access Site Monitoring
Common / Usual Name	Hemodialysis access site patency monitoring software
Classification Name	System, Hemodialysis, Access Recirculation Monitoring
Equivalent Devices	Vasc-Alert (K030456)

Device Description

Vasc-Alert is a software program for alerting dialysis center personnel of an increased risk of access site stenosis for individual hemodialysis patients. Vasc-Alert utilizes measurements routinely collected during a dialysis treatment by the hemodialysis machine, such as pressure and flow rate, and applies a previously published algorithm called the Vascular Access Pressure Ratio (VAPR) test to these measurements. The average VAPR test result for each treatment session is stored in a Vasc-Alert database. If a patient has a high reading in three consecutive dialysis sessions, a report is issued to the medical staff indicating that the patient should be examined more closely for the onset of stenosis. Hemodialysis center personnel can use the report as a tool to proactively monitor for incipient stenosis and prompt proactive intervention to avoid site closure.

Vasc-Alert comprises five main components or modules:

- A module for recording, transferring and parsing data collected by dialysis center machines.
- A module for calculating the VAPR values from treatment data.
- A module for identifying significant patterns in the calculated VAPR data that will prompt an alert (i.e., 3 high readings in a row for a patient).
- A module for generating reports and sending these out to center personnel.
- An internet-based data input module.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. John B. Kennedy
President
Vasc-Alert, LLC
1807 W. Sunnyside Avenue, Suite 301
CHICAGO IL 60640

Re: K042566
Trade/Device Name: Vasc-Alert
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 MQS
Dated: September 17, 2004
Received: September 21, 2004

Dear Mr. Kennedy:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K042566
(Note: original submission for Vasc-Alert was K030456)

Device Name: Vasc-Alert

Indications for Use:

Vasc-Alert vascular data analysis software is intended for use by Healthcare professionals in a non-critical care setting for assessment of increased risk of access site stenosis in patients with grafts and fistulas, as an aid for vascular access site management. The software is to be used with data generated from hemodialysis machines.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042566

Prescription Use ✓
(Per 21 CFR 801.109)