K030456

JUL 11 2003

510(K) SUMMARY

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: December 30, 2002

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	The Transonic HD01 Hemodialysis Monitor (K960817 and K980906), and Medisystems Access Alert (K002372).

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.

Intended 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, as an aid for vascular access site management. The software is to be used with data generated from hemodialysis machines manufactured by Fresenius and Cobe/Gambro.

Substantial Equivalence Comparison

The Vasc-Alert device is substantially equivalent to both the Transonic Flow Monitor and the Access Alert product because it has the same intended use (detection of the buildup of stenosis in the access site), and has proven in side-by-side testing that they can detect the same 'at risk' patients. The devices cited as equivalent also use essentially the same technology in their deriving their analysis (pressure and flow). Access Alert uses the same physical measurements as an indication of stenosis (pressure measurement). The Transonic Flow Monitor measures flow, which is directly related to pressure because of Bernoulli's Principle. While Vasc-Alert identified more patients at risk than the other technologies, the majority of these patients did in fact develop complications in their access sites within 3 months, proving that Vasc-Alert can be used as an indication of stenosis developing in the access site.

Safety and Effectiveness

The system is considered to be a MINOR risk for users and patients because:

- it does not control a life supporting or life-sustaining device,
- it does not control the delivery of potentially harmful energy,
- it does not control treatment delivery,
- it does not provide diagnostic information on which treatment or therapy is based, such that if misapplied it could result in serious injury or death,
- it does not perform vital signs monitoring.

As a practical matter, the reports generated by Vasc-Alert merely prompt medical staff to examine the patient more closely to confirm the degree of stenosis present and its location. Such an examination is common practice prior to any intervention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

Mr. John Kennedy
President
Vasc-Alert L.L.C.
1807 W. Sunnyside Suite 301
CHICAGO IL 60640

Re: K030456
Trade/Device Name: Vasc-Alert
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis systems and accessories
Regulatory Class: II
Product Code: 78 KOC
Dated: June 13, 2003
Received: June 16, 2003

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 (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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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): K030456

Device Name: Vasc-Alert

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lepmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030456