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2 510(k) Summary

Date Prepared: July 30, 2012

Submitter's Name / Contact Person

Manufacturer

Vascular Solutions Zerusa Limited
208 Business Innovation Centre
NUI Galway, Newcastle Road
Galway, IRELAND
Tel: 011-353-91-861611
Establishment Registration # 3005395947

Contact Person

Jennifer Ruether
Sr. Regulatory Product Specialist
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369
Tel: 763-656-4300; Fax: 763-656-4250
Establishment Registration # 2134812

General Information

Trade Name	Guardian® II and Guardian® II NC
Common / Usual Name	Hemostasis Valves
Classification Name	870.4290; DTL; Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting; Class II
Predicate Devices	K101113 – Guardian II NC (Vascular Solutions Zerusa Limited) K092711 – Guardian II (Vascular Solutions Zerusa Limited)

Device Description

The Guardian hemostasis valves are designed to be used as conduits when interventional devices with diameters up to 8 F are inserted into the human vascular system. The devices have two seals: the low-pressure seal and the high-pressure seal. Closure of the high-pressure seal, which is achieved when the nut can no longer rotate, secures the diagnostic/ interventional device in position within the vasculature and allows for pressure injections up to 600 psi (40 ATM).

A guidewire introducer and guidewire torque device may be included with the Guardian II and Guardian II NC hemostasis valves.

Intended Use/Indications for Use

Guardian hemostasis valves are intended to maintain hemostasis during the use of diagnostic or interventional devices. Guardian hemostasis valves are indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8F (0.105" or 2.67 mm) during diagnostic/ interventional procedures.

The torque device is provided as an aid in steering the guidewire within the vascular anatomy.

Technological/Performance Characteristics

The Guardian II devices consist of the same materials and design as the predicate devices. Labeling changes have been implemented. The pressure injection upper limit has been changed from 150 psi to 600 psi; bench testing confirmed the devices are capable of performing as intended at the increased pressure injection limit.

Substantial Equivalence and Summary of Studies

The Guardian II devices are substantially equivalent to the currently marketed predicate devices, based on comparisons of the device classifications, technological characteristics, and the indications for use. Bench test results support the pressure injection upper limit modification. The bench test results did not raise new safety or performance questions and confirmed that the Guardian II devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 7 2012

Vascular Solutions Zerusa Limited
c/o Ms. Jennifer Ruether
Sr. Regulatory Product Specialist
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369

Re: K122301
Trade/Device Name: Guardian® II and Guardian® II NC
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold or Fitting
Regulatory Class: Class II
Product Code: DTL
Dated: July 30, 2012
Received: August 1, 2012

Dear Ms. Ruether:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

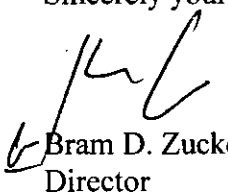
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

K122301

Indications for Use

510(k) Number (if known): K122301

Device Name: Guardian® II and Guardian® II NC Hemostasis Valve

Indications for Use:

Guardian hemostasis valves are intended to maintain hemostasis during the use of diagnostic or interventional devices. Guardian hemostasis valves are indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8F (0.105" or 2.67 mm) during diagnostic/ interventional procedures.

The torque device is provided as an aid in steering the guidewire within the vascular anatomy.

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

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122301

(Posted November 13, 2003)