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NOV 2 1 2005

510(K) SUMMARY

1. SUBMITTER:

Zerusa Limited
219-220 Business Innovation Centre, NUIG
Galway, Ireland
Telephone: 011-353-91-861611
Establishment Registration Number: Pending

Official contact: Ms. Oonagh Sweeney, Quality Systems Manager
Phone: 011-353-91-863062
Date Prepared: August 24, 2005

2. DEVICE:

Tradename:	Guardian Hemostasis Valve with Guidewire Introducer
Classification Name:	Cardiopulmonary Bypass Adaptor, Stopcock, Manifold or Fitting
Classification:	Class II
Common Name:	Hemostatic Valve
Product Code:	74 DTL
Regulation Number:	870.4290

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the Zerusa Limited Guardian Hemostasis Valve were the CoPilot Bleedback Control Valve marketed by Guidant (#K991102) and the EasyPass Y-connector Hemostatic Valve marketed by Millimed A/S (#K042060).

4. DEVICE DESCRIPTION:

The Zerusa Guardian™ Hemostasis Valve is designed to be used as a conduit for which interventional devices with diameters up to 8.0F are inserted into the human vascular system.

The device has two seals: the low-pressure seal and the high-pressure seal. Depressing the cap engages the Quikloc™ to open the low-pressure seal, depressing the cap again closes the seal. The high-pressure seal is operated by rotating the nut clockwise.

Closure of the high-pressure seal secures the diagnostic/interventional device in position within the vasculature and also allows for pressure injections. The two independently operated seals allow for minimal blood loss during vascular procedures. When the low pressure seal is open, it allows the device to be flushed. During the procedure, the low pressure seal is opened in order to allow the advancement/withdrawal of diagnostic/interventional devices.

Included with the Guardian™ Hemostasis Valve is a Guidewire Introducer, which is used to facilitate entry of the guidewire into the hemostasis valve. The Guidewire Introducer has an effective length of 125mm (4.9") and an inside diameter of 0.6mm (or 0.023").

5. INTENDED USE:

The Guardian HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8.0F (2.67 mm or 0.105") during diagnostic/interventional procedures. The guidewire introducer is included to facilitate the guidewire's passage through the Guardian HV.

6. INDICATIONS FOR USE:

The Guardian HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8.0F (2.67 mm or 0.105") during diagnostic/interventional procedures. The guidewire introducer is included to facilitate the guidewire's passage through the Guardian HV.

7. COMPARISON OF CHARACTERISTICS:

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate devices.

8. PERFORMANCE DATA:

The Guardian Hemostasis Valve with Guidewire Introducer was subjected to a full battery of performance testing. The results of the performance testing demonstrated the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2005

Zerusa Limited
c/o Ms. Oonagh Sweeney
Quality Systems Manager
219-220 Business Innovation Centre, NUIG
Galway, Ireland

Re: K052381
Guardian Hemostasis Valve with Guidewire Introducer
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II (Two)
Product Code: DTL
Dated: August 24, 2005
Received: August 30, 2005

Dear Ms. Sweeney:

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 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 (240) 276-0120. 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 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/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

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

Enclosure

K052381

510(k) Number (if known): #K052381

Device Name: Guardian Hemostasis Valve with Guidewire Introducer

Indications for Use: The Guardian HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8.0F (2.67 mm or 0.105") during diagnostic/interventional procedures. The guidewire introducer is included to facilitate the guidewire's passage through the Guardian HV.

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Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Donna R. Kuchner

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510(k) number K052381