

K090022

510(k) Summary

APR 20 2009

Contact: Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
(646) 460-2984

Device Trade Name: Paradis Vaso Shield™

Manufacturer: SpineMedica, LLC
811 Livingstone Court, Suite B
Marietta, GA 30067

Classification: 21 CFR §TBD, Vessel Guard

Class: II

Product Code: MFX

Indications For Use:

The SpineMedica *Paradis Vaso Shield*™ is indicated as a cover for vessels following anterior vertebral surgery.

Device Description:

The SpineMedica *Paradis Vaso Shield*™ is a flexible sheet of 30 Wt.% polyvinyl alcohol (PVA) material with dimensions of 60 ±6 mm X 100 ±10 mm and a thickness of 1.0 ±0.2 mm. The corners of the sheet are rounded. There are no holes or perforations. There are no markings on either side of the sheet, raised (embossed) or printed. The sheet is provided sterile and hydrated in saline solution.

Predicate Device(s):

The SpineMedica *Paradis Vaso Shield*™ was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and/or materials.

Performance Standards:

Testing performed indicates the SpineMedica *Paradis Vaso Shield*™ is substantially equivalent to predicate devices.

Summary of Safety and Effectiveness:

As part of the Pre-market Notification (510(k)) submission, non-clinical evaluation of the SpineMedica *Paradis Vaso Shield*™ included the following to establish safety and effectiveness:

- a. **Biocompatibility Testing**
Testing was completed to verify that the SpineMedica *Paradis Vaso Shield*[™] composed of the SpineMedica hydrogel has acceptable biocompatibility for use as a permanently implanted device.
- b. **Evaluation of Device in a Simulated Clinical Environment**
The SpineMedica *Paradis Vaso Shield*[™] was evaluated in a simulated clinical environment to demonstrate that the design of the device meets the needs of the user.
- c. **Clinical Literature Review**
A clinical literature review was conducted to validate the design of the SpineMedica *Paradis Vaso Shield*[™].
- d. **Other Testing**
Other testing included: dimensional analysis, package integrity, suture pull out strength, pyrogenicity, shelf-life, distribution simulation, environmental conditioning, and sterilization validation. All testing results met required acceptance criteria.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SpineMedica, LLC
c/o Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518

APR 20 2009

Re: K090022
Trade Name: SpineMedica Paradís Vaso Shield™
Regulation Number: 870.3470.
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II (Two)
Product Code: OMR
Dated: April 14, 2009
Received: April 16, 2009

Dear Mr. Guthner:

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). You may, therefore, market the device with a 6 month shelf life, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling and any promotional materials:

The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established.

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Furthermore, the indication for use as a cover for vessels following anterior vertebral surgery must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

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

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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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

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toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
<http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'D. Tillman', with a long horizontal flourish extending to the right.

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090022

Device Name: SpineMedica Paradis Vaso Shield™

Indications For Use: The Paradis Vaso Shield™ is indicated for use as a cover for vessels following anterior vertebral surgery.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

