K101805

APR - 8 2011

510(k) Summary

Proprietary Name: *HydroFix™ Vaso Shield*

Common Name: Vessel Guard or Cover

Classification Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene. (per 21 CFR 870.3470)

Device Class: Class II

Product Code: OMR

Classification Panel: Cardiovascular Devices

Establishment Registration: 3006731846

Contact:

Sally Thorsen
MiMedx Group, Inc.
811 Livingston Court SE, Suite B
Marietta, GA 30067
(678) 384-6720
Fax 678-384-6741
sthorsen@mimedx.com

Performance Standards:

Performance standards do not currently exist for these devices.

Device Description:

The MiMedx *HydroFix™ Vaso Shield* is a flexible sheet of polyvinyl alcohol (PVA) material provided in various dimensions. It is a slippery, clear pliable, conformable, nanoporous permanent vessel cover that minimizes tissue contact between the vessels and the spine. 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.

Indications For Use:

The MiMedx *HydroFix™ Vaso Shield* is indicated as a cover for vessels during anterior vertebral surgery.

Substantially Equivalent Devices:

The following devices as substantially equivalent predicate devices listed below.

K090022 *Paradis Vaso Shield™*
K093551 *Paradis Vaso Shield™*

K100905 *HydroFix™ Vaso Shield*
K061727 Gore PRECLUDE® Vessel Guard

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

Intended Use: Fusion Surgery, Adjacent Level Surgery, Artificial Disc Implantation, Implant or Hardware Removal, Trauma, Vascular Surgery in the Spine

Brief Comparison Summary:

To demonstrate substantial equivalence of the MiMedx *HydroFix™ Vaso Shield* to the predicate devices, technological characteristics and performance criterion were evaluated using *in vivo* testing as indicated below:

***In Vivo* Testing**

- Large Animal Implantation – A sheep model (animal study) was conducted to demonstrate the reduction in the risk of potential vessel damage during anterior vertebral revision surgery. The implanted devices allowed a separation of the soft tissue adjacent to the study site from the study site.

Conclusion:
The sponsor believes that the data and information presented in this 510(k) application, including in vivo testing, and numerous device similarities support a determination of substantial equivalence, and therefore market clearance of the MiMedx *HydroFix™ Vaso Shield* through this 510(k) Premarket Notification.

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

APR - 8 2011

MiMedx Group, Inc.
c/o Mr. William Jackson
811 Livingston Court SE
Suite B
Marietta, GA 30067

Re: K101805
Trade Name: HydroFix Vaso Shield™
Regulation Number: 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: OMR
Dated: March 15, 2011
Received: March 16, 2011

Dear Mr. Jackson:

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.

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

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,

Christy Foreman

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101805

Device Name: MiMedx HyroFix Vaso Shield™

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

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

Donna R. Vo Ames

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101805