K060973

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

Revised July 20, 2006

JUL 26 2006

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of Vycor Medical LLC Joseph Azary can be contacted by telephone at (203) 944-9320 or fax at (203) 944-9317. Mailing address; 543 Long Hill Avenue, Shelton, CT 06484.

Vycor Medical LLC is located at 40 Chardonnay Drive, Coram, NY 11727. The establishment registration for Vycor Medical is pending.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Possible device trade names are:

- Vycor ViewSite Access System
- Vycor ViewSite Brain Access System (VBAS)
- Vycor ViewSite Spinal Access System (VSAS)

Device Common, Usual, or Classification Names

Retractor, Retractor for Neurosurgery, Brain Retractor, Self Retaining Retractor

Classification Panel

Classification of this device would fall under the responsibility of the Division of General, Restorative and Neurological Devices.

Class

Classification: Class 2

Product Code: GZT, 21 CFR 882.4800

Description of the Device [21 CFR 807.92(a)(4)]

The Vycor Medical Surgical Access Systems include a family of retractor devices of varying shapes and sizes designed for providing diagnostic and surgical access to various portions of the brain and spinal region.

The variety of devices include:

- Brain Access System including three models of varying shapes and sizes.
    - TC model (elliptical diameters 2.1cm or 1.7cm, lengths 3,5,7, or 9 cm)
    - EC model (3.4 cm diameter, 3,5, 7 cm lengths)
    - SF model (channel 2.2cm or 2.5cm, length 3,5, or 7 cm)
- Spinal Access System
    - (aperture widths are 2.6 to 5.4 cm, and 3 or 5cm access channel height)

Each device consists of an introducer and port. The port and introducer are packaged assembled and ready for use. Upon insertion of the device, the introducer is removed and the port is left in place. The introducer has a length greater than the port. The smooth and soft tapered introducer works to spread

apart the brain or other portions of delicate tissue. Upon removal of the introducer, the port provides a hollow working channel allowing the surgeon access to the target tissues.

The port is transparent to allow direct visualization of the underlying retracted anatomical structures. The retractors are light weight, non-conductive, and are compatible with Lelya positioning clamps to provide fixation and reduce accidental movement.

The spinal access device can access the spine for surgical procedures. The spinal access device has three components including the introducer, port, and fixation screws. The fixation screws are used to hold the device in place during the surgery. The fixation screws are temporarily screwed into surrounding bone tissue during the surgical procedure.

Packaging

The devices will be packaged in a heat sealed off the shelf low density polyethylene pouch.

The types of pouches have been utilized for medical devices for many years and are compatible with gamma radiation sterilization.

The pouches will be placed in different sized labeled boxes depending on the model.

Intended Use [21 CFR 807.92(a)(5)]

To provide for access and allow for visualization of the surgical field during brain and spinal surgery.

Technological Characteristics [21 CFR 807.92(a)(6)]

Vycor Medical LLC believes that the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The device complies is composed of materials that either have a long history of usage in the medical community or have passed biocompatibility testing requirements.

Predicate Device [21 CFR 807.92(a)(3)]

The predicate devices are listed as follows:

For Spinal Indications:

- Medtronic – Mast Quadrant Retractor System – K043602

For Brain Indications:

- V. Mueller – Brain Retractor – K895395
- Budde Halo Retractor - K830332
- Compass Stereotactic System – Retractor - K896156

Conclusion [21 CFR 807.92(b)(3)]

We believe the differences between the subject device and predicate device are minor and conclude that the subject devices are as safe and effective as the predicate devices.

What about the cohesive gel?

The question about 18 years for saline and 22 years for silicone is a problem. I can think of no answer other than "the potential consequences of rupture are greater, in part because of silent rupture..."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

Vycor Medical LLC
% TUV Rheinland of North America, Inc.
Mr. Tamas Borsai
12 Commerce Road
Newton, Connecticut 06470

Re: K060973
Trade/Device Name: Vycor ViewSite Surgical Access System
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining retractor for neurosurgery
Regulatory Class: II
Product Code: GZT
Dated: July 7, 2006
Received: July 11, 2006

Dear Mr. Borsai

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) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060973

Device Name: Vycor ViewSite Surgical Access System

Indications For Use:

To provide for access and allow for visualization of the surgical field during brain and spinal surgery.

Prescription Use ___X___ 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)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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