

**5. 510(k) Summary according to 807.92(c) JUL 14 2008**

**Contact:** Thomas Hoghaug  
Signus Medical  
18888 Lake Drive East  
Chanhassen, MN 55317  
952-294-8700

**Trade Name:** MonoPoly Pedicle Screw System

**Classification:** 21 CFR §888.3070 Pedicle screw spinal system  
§888.3050 Spinal interlaminar fixation orthosis

**Class:** III

**Product Codes:** NKB, KWP, MNH, MNI

**Indications for Use:**

The MonoPoly Pedicle Screw System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine (T1-S1), specifically as follows:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the is indicated for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) spinal tumor, and/or (6) failed previous fusion (pseudarthrosis).

When used as a non-cervical and non-pedicle screw fixation system, the MonoPoly Pedicle Screw System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) trauma (fracture, dislocation), (5) pseudarthrosis, (6) tumor resection and/or (7) failed previous fusion.

**Device Description:**

The MonoPoly Pedicle Screw System is comprised of a variety of monoaxial and polyaxial pedicle screws sizes, couplers, a set screw, cross links, a washer, rods and hooks. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ElI).

**Predicate Device(s):**

The MonoPoly Pedicle Screw System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These devices include the Cross Medical Synergy VLS System (K974749), the U&I Optima Xia System (K031585), The GSS Medical GS System (K053573) and the Signus Medical OvalTwist System (K061577)

**Performance Testing:**

The pre-clinical testing performed indicated that the MonoPoly Pedicle Screw System is substantially equivalent to predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Signus Medical  
% Mr. Thomas Hoghaug  
18888 Lake Drive East  
Chanhassen, MN 55317

JUL 14 2008

Re: K081108  
Trade/Device Name: MonoPoly Pedicle Screw System  
Regulation Number: 21 CFR 888.3070  
Regulation Names: Pedicle screw spinal system  
Regulatory Class: III  
Product Code: NKB, MNI, MNH, KWP  
Dated: April 17, 2008  
Received: April 18, 2008

Dear Mr. Hoghaug:

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.

Page 2 – Mr. Thomas Hoghaug

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

#### 4. Indications for Use

510(k) Number (if known): K081108

Indications for Use:

The MonoPoly Pedicle Screw System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine (T1-S1), specifically as follows:

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Prescription Use   
(Part 21 CFR 801 Subpart D)

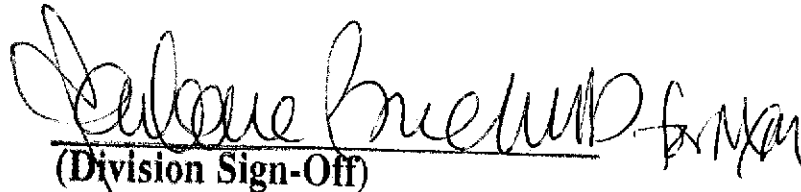
AND/OR

Over-The-Counter Use   
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K081108