



AUG 25 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Signus Medical, LLC.  
c/o Ms. Tracy Gray  
Principal Consultant  
Alquest, Inc.  
4050 Olson Memorial Highway, Suite 350  
Minneapolis, Minnesota 55422

Re: K052096

Trade/Device Name: NUBIC™ Spinal Implant  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: July 29, 2005  
Received: August 4, 2005

Dear Ms. Gray:

This letter corrects our substantially equivalent letter of August 16, 2005. The Company title has been changed to reflect the correct owner of the 510(k), Signus Medical, LLC., as indicated in your 510(k) submission.

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 (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.

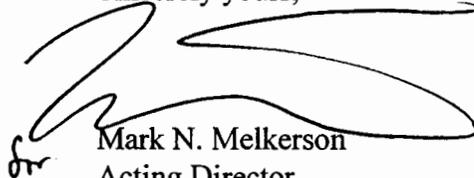
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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" (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 (301) 443-6597 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 "Mark N. Melkerson", is written over a horizontal line. The signature is stylized and somewhat cursive.

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

Enclosure

**Indications for Use Page**

510(k) Number (if known): K052096

Device Name: NUBIC™ Spinal Implant

**Indications for Use:**

The NUBIC™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.

The NUBIC™ may be implanted singularly or in pairs.

The supplemental internal fixation systems that may be used with the NUBIC™ Spinal Implant include, but are not limited to, SIGNUS CONKLUSION System, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 801 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**

SIGNUS Medical LLC. 510(k) Number K052096  
NUBIC™ Special 510(k)

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## 510(k) Summary

<b>Submitter:</b>	SIGNUS Medical, LLC. 18888 Lake Drive East Chanhassen MN. 55317 952-294-8700
<b>Contact Person:</b>	Alan Alexander Vice President Alquest, Inc. Phone: (763) 588-9817 Fax: (763) 287-3836
<b>Date Prepared:</b>	July 29, 2005
<b>Trade Name:</b>	NUBIC™ Spinal Implant
<b>Classification Name and Number:</b>	21 CFR 888.3060
<b>Product Code:</b>	MQP
<b>Predicate Device</b>	RABEA™ cleared under K043316.
<b>Device Description:</b>	<p>The NUBIC™ Spinal implant is a rectangular frame. The upper and lower aspects of the implant are open and the walls feature spikes which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies.</p> <p>The frame is forged from PEEK (PEEK-OPTIMA™ LT1), which is radiolucent, and incorporates small Titanium alloy (TiAl6V4) marker pins so the device can be located within the body. The marker pins meet ASTM F-136 and ISO 5832/3.</p> <p>The NUBIC™ Spinal Implant is available in a variety of sizes ranging from 4mm to 30mm. This enables the surgeon to choose the size suited to the individual pathology and anatomical condition. The NUBIC™ may be implanted individually or in pairs.</p>
<b>Intended Use:</b>	<p>The NUBIC™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.</p> <p>The NUBIC™ may be implanted singularly or in pairs.</p> <p>The supplemental internal fixation systems that may be used with the NUBIC™ Spinal Implant and include, but are not limited to, SIGNUS CONKLUSION System, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).</p>
<b>Statement of Technological Comparison</b>	<p>The subject device and predicate device have the following similarities:</p> <ul style="list-style-type: none"> <li>• The same indication for use;</li> <li>• The same operating principle;</li> <li>• The same basic design;</li> <li>• The same materials;</li> </ul>

	<ul style="list-style-type: none"> <li>• Implanted using the same surgical techniques and equipment;</li> <li>• Used in conjunction with the same types of supplemental internal fixation systems;</li> <li>• The same manufacturing environment;</li> <li>• The same sterilization process; and</li> <li>• The same packaging configurations.</li> </ul> <p>In summary, the NUBIC™, as described in this submission is, in the opinion of Signus Medical, LLC., substantially equivalent to the predicate device.</p>
<b>Conclusion:</b>	<p>The NUBIC™ as modified in this submission, is substantially equivalent to the predicate device, RABEA™ cleared under K043316. This conclusion is based upon the similarities of the devices in terms of functional design, indication for use, principles of operation, materials, and performance characteristics.</p>