510(k) Summary

Nanovis, LLC

Nanovis Intervertebral Body Fusion System

K110442

November 2, 2011

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Nanovis Intervertebral Body Fusion System
Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device
Classification Regulations:	21 CFR 888.3080, Class II
Product Code:	ODP, MAX
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Reviewing Branch:	Orthopedic Spine Devices Branch

INTENDED USE

When used as a cervical intervertebral body fusion device, the Nanovis Intervertebral Body Fusion System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one spinal level from C2-T1. These patients should have had at least six weeks of non-operative treatment. Nanovis Intervertebral Body Fusion System implants are to be used with autogenous bone graft and in combination with supplemental fixation indicated for cervical fusion procedures.

When used as a lumbar intervertebral body fusion device, the Nanovis Intervertebral Body Fusion System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). Nanovis Intervertebral Body Fusion System implants are to be used with autogenous bone graft and in combination with supplemental fixation indicated for lumbar spinal fusion procedures.

DEVICE DESCRIPTION

The Nanovis Intervertebral Body Fusion System consists of implants (cages) and related instruments intended to be used for intervertebral body fusion procedures involving the cervical (C2 - T1) and lumbar (L2 - S1) spine. The cages are available in a variety of shapes and sizes to accommodate the individual anatomic and clinical circumstances of each patient, and are available in two materials: polyetheretherketone (PEEK) and titanium alloy (Ti-6Al-4V ELI).

EQUIVALENCE TO MARKETED DEVICE

Nanovis, LLC submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the Nanovis Intervertebral Body Fusion System is substantially equivalent in indications and design principles to the following predicate devices each of which has been determined by FDA to be substantially equivalent to pre-amendment devices, or that were the subject of approved PMA applications and were subsequently reclassified as Class II devices:

LDR Spine Cervical Interbody Fusion System from LDR Spine USA, K091088;

Novel® Spinal Spacer System from Alphatec Spine, Inc., K081730;

Choice Spine Cervical Interbody Spacer System from Choice Spine, LP, K091531;

CORNERSTONE® PSR Spinal System from Medtronic Sofamor Danek, K100214;

Synthes Oracle Spacer from Synthes Spine, K072791;

L-Varlock Lumbar Cage from Kiscomedica, S.A., K080537;
WAVE and LOOP Cages from Advanced Medical Technologies AG, K080401;
Ardis Spacer from Abbot Spine, Inc. (now Zimmer Spine), K073202;
Lumbar I/F Cage with VSP Spine System from DePuy AcroMed, P960025; and
Spinal USA Intervertebral Body Fusion Device from Spinal USA, K080314, K081196, and K092193.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of the same materials, have similar overall shape, and encompass the same range of physical dimensions including height, width, depth, and lordosis. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. Any differences in technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Performance testing to demonstrate substantial equivalence included methods described in the standards ASTM F2077 (static and dynamic axial compression, and static and dynamic torsion), ASTM F2267 (subsidence), and the draft standard ASTM F04.25.02.02 (expulsion).

Overall, the Nanovis Intervertebral Body Fusion System is similar to the predicate devices in intended use, design principles, materials and overall dimensions.

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

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Nanovis, LLC
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Kevin A. Thomas, PhD
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K110442
Trade/Device Name: Nanovis Intervertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: October 04, 2011
Received: October 04, 2011

Dear Dr. Thomas:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin J. Keith

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

Enclosure

Indications for Use

510(k) Number: K110442

Device Name: Nanovis Intervertebral Body Fusion System

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When used as a lumbar intervertebral body fusion device, the Nanovis Intervertebral Body Fusion System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). Nanovis Intervertebral Body Fusion System implants are to be used with autogenous bone graft and in combination with supplemental fixation indicated for lumbar spinal fusion procedures.

Prescription Use __X__ (Part 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 Surgical, Orthopedic, and Restorative Devices

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