K073669
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6. 510(k) Summary

Sponsor:	Choice Spine, LP 314 Erin Drive, Suite 102 Knoxville, TN 37919 Phone: 865.246.3333 Fax: 865.246.3334
Contact Person:	G. Todd Hawkins. Director of Regulatory Affairs / Quality Assurance
Proposed Proprietary Trade Name:	ORIA Natura Spacer
Classification Name	888.3060 – Spinal Intervertebral Body Fixation Orthosis, 888.3080 – Spinal Intervertebral Body Fusion Device
Device Product Code:	MQP, MAX
Device Description:	The ORIA Natura has a basic rectangular shape, a hollow center for placement of bone graft and a smooth bullet-shaped anterior surface. It is available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements.
Intended Use:	When used as an intervertebral body fusion device, the ORIA Natura Spacer is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (e.g., ORIA Claris, ORIA Spinal Clip System, etc.) and with autograft to facilitate fusion. When used as a vertebral body replacement device, the ORIA Natura Spacer is intended for use in the thoracic and lumbar spine, from T1 to L5, for the replacement of a collapsed or unstable vertebral body resulting from a tumor or traumatic injury. The device system is designed for use with supplemental fixation (e.g., ORIA Claris, ORIA Spinal Clip System, etc.) and with autograft to facilitate fusion.
Materials:	The ORIA Natura Spacer components are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio™) as described by ASTM F2026. Integral radiopaque markers are manufactured from tantalum as described by ASTM F560.
Substantial Equivalence:	Documentation was provided which demonstrated the ORIA Natura Spacer to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

FEB 13 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2008

Choice Spine, LP
% Ms. Karen Warden
Regulatory Affairs Specialist
8202 Sherman Road
Chesterland, OH 44026-2141

Re: K073669
Trade/Device Name: ORIA Natura Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: December 21, 2007
Received: December 26, 2007

Dear Ms. Warden:

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 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

5. Indications for Use Statement

510(k) Number: K073669

Device Name: ORIA Natura Spacer

Indications for Use:

When used as an intervertebral body fusion device, the ORIA Natura Spacer is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (e.g., ORIA Claris, ORIA Spinal Clip System, etc.) and with autograft to facilitate fusion.

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Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marlene Brecht

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073669