K112801

MAY - 1 2012

510(k) Summary

Manufacturer: Qualgenix LLC
1 Jack's Hill Road (Unit 3E)
Oxford, CT 06478
(203) 982 – 4239

Device Trade Name: Ayers Rock Cervical Cage

Contact: Richard Deslauriers, M.D.
CEO

Date Prepared: September 21, 2011

Classification: §888.3080; Intervertebral body fusion device

Class: II

Product Code: ODP

Indications For Use: The Qualgenix Ayers Rock Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. These patients should have had 6 weeks of non-operative treatment. The Qualgenix Ayers Rock Cervical Cage implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The Qualgenix Ayers Rock Cervical Cage is to be used with supplemental fixation.

Device Description: The Ayers Rock Cervical Cage consists of cervical spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Ayers Rock Cervical Cage is manufactured from PEEK OPTIMA LT1 polymer. The Ayers Rock Cervical Cage is for single level anterior spinal use from the C2-C3 to C7-T1 disc levels.

Predicate Device(s): The Ayers Rock Cervical Cage was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, and function. Predicate devices include the LDR Spine MC+ (K080588) and SpineArt Tryptik (K091873).

Performance Standards: Preclinical testing has been performed per ASTM F2077 (static compression, compression-shear, static torsion, dynamic compression), expulsion testing, and ASTM F2267 (subsidence testing) indicating that the Ayers Rock Cervical Cage is substantially equivalent to predicate devices.

Conclusion: Comparisons of device indications, intended use, design, and performance were made to predicate devices in order to determine substantial equivalence.

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

Qualgenix LLC
% Richard Deslauriers, M.D.
CEO
1 Jack's Hill Road (Unit 3E)
Oxford, Connecticut 06478

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Re: K112801
Trade/Device Name: Ayers Rock Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: April 3, 2012
Received: April 4, 2012

Dear Dr. Deslauriers:

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,

For Peter Rumm
Dep Cen Dir

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 (if known): K-112801

Device Name: Qualgenix Ayers Rock Cervical Cage

The Qualgenix Ayers Rock Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. These patients should have had 6 weeks of non-operative treatment. The Qualgenix Ayers Rock Cervical Cage implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The Qualgenix Ayers Rock Cervical Cage is to be used with supplemental fixation.

Prescription Use ___V___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112801