MAY - 1 2012

510(k) Summary

Contact:	Dr. Richard Deslauriers Chairman, Qualgenix, LLC (203) 982 – 4239
Device Trade Name:	Mont Blanc Pedicle Screw System
Manufacturer:	Qualgenix, LLC 1 Jack's Hill Rd (Unit 3E) Oxford, CT 06478
Date Prepared:	September 7, 2011
Common Name:	Pedicle screw spinal system
Classification:	21 CFR §888.3070
Class:	III
Product Code:	NKB, MNH, MNI
Indications For Use:	The Mont Blanc Pedicle Screw System is intended for noncervical pedicle fixation from the T1 to S1 vertebrae in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.
Device Description:	The Mont Blanc Pedicle Screw System is comprised of a variety of monoaxial and polyaxial pedicle screws and rods. The rods are provided straight and intended to interface with the screws, which are traditional saddle design. This device is intended to be used with bone graft to provide immobilization and stabilization of a spinal segment as an adjunct to fusion. The Mont Blanc Pedicle Screw System is fabricated from wrought Ti-6Al-4V (ISO 5832-3).

Predicate Devices: The Mont Blanc 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. Cleared devices include the DePuy MOSS Miami (K962628), Biomet Synergy VLS Open (K973836), Synthes Pangea (K052123) and Zimmer Silhouette (K993067).

Performance Testing: Testing performed indicates the Mont Blanc Pedicle Screw System is substantially equivalent to predicate devices. Testing included mechanical testing per ASTM F1717, including static and dynamic compression bending and static torsion.

Conclusion: The Mont Blanc Pedicle Screw System has the identical indications for use, intended use, design, and performance compared to predicate devices.

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.
Chairman
1 Jack's Hill Road, Unit 3E
Oxford, Connecticut 06478

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Re: K112684
Trade/Device Name: Mont Blanc Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: March 28, 2012
Received: March 30, 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

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

Enclosure

4. Indications for Use

510(k) Number (if known): K112684

Device Name: Mont Blanc Pedicle Screw System

The Mont Blanc Pedicle Screw System is intended for noncervical pedicle fixation from the T1 to S1 vertebrae in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Prescription Use ___√___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K112684