



Food and Drug Administration
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April 12, 2016

Icotec AG
% Mr. Samuel Pollard
Associate, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K151977
Trade/Device Name: icotec Pedicle System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: March 14, 2016
Received: March 15, 2016

Dear Mr. Pollard:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K151977

Device Name

icotec Pedicle System

Indications for Use (Describe)

The icotec Pedicle System is intended to provide immobilization and stabilization of the posterior, noncervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (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; pseudoarthrosis; and failed previous fusion.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Device Trade Name: icotec Pedicle System

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Date Prepared: December 17, 2015

Classification: 21 CFR §888.3070: Pedicle screw spinal system

Class: III

Product Code: NKB, MNI, MNH

Primary Predicate: CoreLink Tiger Spine System (K113058)

Additional Predicate: Amedica Valeo PS System (K072022)

Indications for Use:

The icotec Pedicle System is intended to provide immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (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; pseudoarthrosis; and failed previous fusion.

Device Description:

The icotec Pedicle System is a posterior pedicle screw system manufactured from titanium alloy (Ti6Al4V ELI per ASTM F136) designed for fixation of the non-cervical spine. The icotec Pedicle System is comprised of monoaxial and polyaxial pedicle screws and curved and straight rods. The icotec Pedicle System can be used for single or multiple level fixations.

Predicate Devices:

The icotec Pedicle System is substantially equivalent to the primary predicate CoreLink Tiger Spine System (K113058) and reference predicate Amedica Valeo PS System (K072022) with respect to intended use, material, geometry, method of fixation, and mechanical properties. Mechanical testing, including static and dynamic compression bending and static torsion testing, has demonstrated substantial equivalence to previously cleared devices.

Preclinical Testing:

The non-clinical tests performed by the company include static compression bending, static torsion, and dynamic compression bending testing per ASTM F1717 of the worst case pedicle screw system. The results of the performed tests demonstrate that the icotec Pedicle System is substantially equivalent to legally marketed predicate devices.

Conclusion:

The purpose of the traditional 510(k) is to receive regulatory clearance to introduce the icotec Pedicle System to interstate commerce. Substantial equivalence has been demonstrated to the cited predicate devices.