



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 9, 2017

Kalitec Direct, LLC
% Mr. J.D. Webb
Official Correspondent
The Orthomedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K170342
Trade/Device Name: Ocata™ Anterior Cervical System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 31, 2017
Received: February 3, 2017

Dear Mr. Webb:

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 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,

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)

K170342

K170342

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Device Name

Ocata™ Anterior Cervical System

Indications for Use (Describe)

The Ocata™ Anterior Cervical System is intended for anterior interbody screw fixation of the cervical spine from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine as an adjunct to fusion for patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures and dislocations), tumors, spondylolisthesis, deformity (defined as kyphosis, lordosis, or scoliosis), spinal stenosis, pseudarthrosis, and/or failed previous fusions. This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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: Ocata™ Anterior Cervical System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	January 31, 2017
Submitted By	Scott Winn Kalitec Direct, LLC 618 E. South Street, Suite 500 Orlando, FL 32801 407-545-2063 Tele 407-358-5441 Fax
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Secondary Contact	Keith Cannan 1890 W. CR 419, Suite 2000 Oviedo, FL 32765 407-545-2063 Tele 407-358-5441 Fax e-mail: quality@kalitecdirect.com
Trade Name	Ocata™ Anterior Cervical System
Common Name	Anterior Cervical Plate System
Classification Name	Appliance, Fixation, Spinal Intervertebral Body
Class	II
Product Code	KWQ
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	Theken Surgical Tether™ ACFS – K010466
Additional Predicate Devices	Integra Sonoma™ Cervical Plate System - K032368 Stryker Reflex™ Anterior Cervical Plate System – K062310 and K040261 Synthes CLSP Cervical Plate – K000536
Device Description	The Ocata Anterior Cervical System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The Ocata Anterior Cervical System consists of a variety of shapes and sizes of bone plates, screws (available in self-drilling or self-tapping, fixed or variable configurations), and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The Ocata™ Anterior Cervical System implant components are made from titanium alloy.

Materials	Implants are made from Ti-6Al-4V ELI conforming to ASTM F136. System specific instruments are made from either 17-4 H900 SS or 465 SS H950 conforming to ASTM F899.
Intended Use	Maintain adequate disc space until fusion occurs.
Substantial Equivalence Claimed to Predicate Devices	The Ocata™ Anterior Cervical System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The Ocata™ Anterior Cervical System is intended for anterior interbody screw fixation of the cervical spine from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine as an adjunct to fusion for patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures and dislocations), tumors, spondylolisthesis, deformity (defined as kyphosis, lordosis, or scoliosis), spinal stenosis, pseudarthrosis, and/or failed previous fusions. This device system is intended for anterior cervical intervertebral body fusions only. WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
Non-clinical Test Summary	The following analyses were conducted: - Plates were tested for static and dynamic compression and torsion per ASTM F1717 - Screws were tested for torsional yield strength, driving torque, and axial pullout strength per ASTM F543 The results of these evaluations indicate that the Ocata™ Anterior Cervical System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Kalitec Direct, LLC considers the Ocata™ Anterior Cervical System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use