DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 22, 2017

Kalitec Direct, LLC
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street Northwest, Suite 1000
Washington, District of Columbia 20001

Re: K172086
Trade/Device Name: Matira™ Anterior Cervical System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 8, 2017
Received: September 11, 2017

Dear Mr. Eggleton:

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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172086

Device Name
Matira™ Anterior Cervical System

Indications for Use *(Describe)*
The Matira™ Anterior Cervical System is intended for anterior interbody screw fixation of the cervical spine from C2 to Tl. 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
for the Matira™ Anterior Cervical System

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

Date Prepared	July 6, 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	Mr. Justin Eggleton Senior Director, Spine Regulatory Affairs Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street Northwest, Suite 1000 Washington, District of Columbia 20001 202-552-5800 Tele e-mail: jeggleton@mcra.com
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	Matira™ 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	Ocata Anterior Cervical System™ (K170342)
Secondary Predicate Devices	None
Device Description	The Matira 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 Matira 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. Bone screws inserted into the vertebral body of the cervical spine using an anterior approach provide fixation. The Matira 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 space until fusion occurs.
Substantial Equivalence Claimed to Predicate Devices	The Matira 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 Matira 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 Matira 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 Matira 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.