September 12, 2023

Kyocera Medical Technologies, Inc. (KMTI)
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K231766
Trade/Device Name: Skyway Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ, OVE
Dated: August 18, 2023
Received: August 18, 2023

Dear Nathan Wright:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K231766

Device Name
Skyway Anterior Cervical Plate System

Indications for Use *(Describe)*
The Skyway Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis, or scoliosis), tumor, pseudarthrosis or failed previous fusion.
The 4-Hole 1-Level Plates are limited to use at one contiguous level.

The KMTI Tesera-K SC System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one or two levels from C2-T1 . KMTI Tesera-K SC System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation. When used with the Skyway Anterior Cervical Plate System plates designed with spacer attachment, the assembly takes on the indications of the KMTI Tesera-K SC lnterbody Spacer, with the Skyway Anterior Cervical Plate System acting as the supplemental fixation.

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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K231766 - 510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc. (KMTI)
Submitter's Address:	1200 California Street Redlands, California 92374
Submitter's Telephone:	909-557-2360
Contact Person:	Nathan Wright MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	June 15, 2023
Trade or Proprietary Name:	Skyway Anterior Cervical Plate System
Regulation Name:	Spinal Intervertebral Body Fixation Orthosis, Intervertebral Fusion Device with Integrated Fixation, Cervical
Classification & Regulation #:	Class II per 21 CFR §888.3060, 21 CFR§888.3080
Product Code:	KWQ, OVE
Classification Panel:	Spinal Devices – DHT6B

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Kyocera Medical Technologies, Inc. (KMTI) Skyway Anterior Cervical Plate System consists of anterior cervical plates, bone screws, and a locking screw. The implant components are composed of titanium alloy Ti-6Al-4V ELI per ASTM F136. The Skyway Anterior Cervical Plate System is offered in various sizes to accommodate patient anatomical needs. The subject 1-Level plates are compatible with and may be permanently attached to the Tesera-K SC System interbody spacers.

INDICATIONS FOR USE

The Skyway Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis, or scoliosis), tumor, pseudarthrosis or failed previous fusion.

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TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use

- Materials of manufacture
- Plate styles, levels, and sizes
- Screw sizes
- Design features

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K221049	VariSync Plate System	Zavation Medical Products, LLC	OVE, ODP, KWQ	Primary
K141993	Nakoma ACP System	Alliance Partners, LLC	KWQ	Additional
K060025	Slimplicity Anterior Cervical Plate System	Spinal USA (now Precision Spine)	KWQ	Additional
K152193	Renovis Anterior Cervical Plate System	Renovis Surgical Technologies, Inc.	KWQ	Additional
K223105	Tesera-K SC System	Kyocera Medical Technologies, Inc.	OVE, ODP	Additional

PERFORMANCE DATA

The Skyway Anterior Cervical Plate System has been tested in the following test modes:

- Static compression bending per ASTM F1717
- Dynamic compression bending per ASTM F1717
- Static torsion per ASTM F1717
- Cage-to-Plate Static Dissociation Testing

The results of this non-clinical testing show that the strength of the Skyway Anterior Cervical Plate System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Skyway Anterior Cervical Plate System is substantially equivalent to the predicate devices.