



November 5, 2024

Kyocera Medical Technologies, Inc.
% Nathan Wright
Engineer and Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K243015

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: September 26, 2024
Received: September 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ethan R. Naylor -S

for Ronald P. Jean, Ph.D.

Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological

Enclosure

Indications for Use

510(k) Number (if known)

K243015

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 Interbody 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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510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc. (KMTI)
Submitter's Address:	1289 Bryn Mawr Avenue, Suite A 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:	September 26, 2024
Trade or Proprietary Name:	Skyway Anterior Cervical Plate System
Device Classification 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:	Orthopedic – Spinal (DHT6B)



DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The KMTI Skyway Anterior Cervical Plate System is an anterior cervical plating fixation system consisting of implants and associated instrumentations to provide supplemental fixation between two adjacent cervical vertebral bodies as an adjunct to fusion or for spinal correction. The Skyway Anterior Cervical Plate System is implanted via an anterior surgical approach.

The subject devices proposed in this submission are a line extension of the Skyway Anterior Cervical Plate System (K231766) with the introduction of additional length and configuration options for the 1-Level Plates and 2-hole and 3-hole 1-Level Plates. This subject line extension also includes non-sterile bone screw and locking screw options. The Skyway Anterior Cervical Plate System plates, bone screws, and locking screws are manufactured from Ti-6Al-4V per ASTM F136.

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 predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. The subject and predicate devices have nearly identical technological characteristics and the minor differences in screw self-tapping features do not raise any new questions of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of Manufacture
- Structure and Function and Design Features
- Plate style, Levels, and Sizes
- Screw Sizes

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K231766	Skyway Anterior Cervical Plate System	Kyocera Medical Technologies, Inc.	KWQ, OVE	Primary
K190227	Boomerang™ Anterior Cervical Plate System	Choice Spine, LP	KWQ	Additional

PERFORMANCE DATA

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

- Static torsion per ASTM F1717-22
- Cage to plate disassociation testing

Compression bending per ASTM F1717 was previously performed to the worst-case sizes under K231766 and was not required for this 510(k) submission. 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 device.