November 27, 2023

K&J Consulting Corp.
℅ Jeena Mathai
President
Eerkie Corporation
4027 Runnymeade Drive
Collegeville, Pennsylvania 19426

Re: K233332
Trade/Device Name: Statera-C™ Spinal System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: September 28, 2023
Received: September 29, 2023

Dear Jeena Mathai:

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.

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,

Colin O'neill -S

FDA

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233332

Device Name
Statera-C™ Spinal System

Indications for Use *(Describe)*
The Statera-C™ Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. It is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Statera-C™ Spinal System may be connected to the Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System using corresponding connectors and/or transition rods.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

K&J Consulting
Statera-C™ Spinal System

Submitter:	K&J Consulting Corp. 2260 Glenview Dr, Lansdale PA 19446 Phone: (716) 465-5551 Email: kj.eng.consulting.services@gmail.com
Official Contact	Jeena Mathai Eerkie Corporation 4027 Runnymeade Dr, Collegeville, PA 19426 Phone: (760) 521-5870 Email: mgsharemg@gmail.com

Date Prepared:	November 15, 2023
Device Name:	Statera-C™ Spinal System
Common Name:	Posterior Cervical Screw System Spinal Interlaminal Fixation System
Classification Name:	Posterior Cervical Screw System Spinal Interlaminal fixation orthosis
Classification Number:	21 CFR 888.3075 21 CFR 888.3050
Product Code/ Classification:	NKG, KWP, Class II
Description:	The Statera-C™ Spinal System is a posterior cervico-thoracic fixation system intended to provide stabilization to promote fusion of the cervical spine and upper thoracic spine. The Statera-C™ Spinal System contains rods, polyaxial screws, hooks, set screws, connectors and cross connectors that are made from Titanium alloy and Cobalt Chrome alloy and are available in multiple shapes and sizes. Connecting components can be locked to the rod in various configurations to accommodate individual patient anatomy.
Indications for Use:	The Statera-C™ Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. It is also intended to restore the integrity of the spinal column even in the absence of fusion for

a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Statera-C™ Spinal System may be connected to the Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System using corresponding connectors and/or transition rods.

Performance Data: Non-clinical testing was performed to demonstrate that the subject Statera-C™ Spinal System is substantially equivalent to the predicate device. The following testing was performed in accordance with the ASTM F1717:

- Static compression bending
- Dynamic compression bending
- Static Torsion

The nonclinical tests demonstrate that the Statera-C™ Spinal System is substantially equivalent to the legally marketed predicate devices.

Predicate Device: Primary predicate: Globus Medical – ELLIPSE® and PROTEX® CT Spinal Systems (K150552)

Reference Device: K&J Consulting – Fortis And Hana Anterior Cervical Plate System, Rex Anterior Cervical Plate System, Balteum™ & Balteum-One™ Lumbar Plate System, And Osprey™ Anterior Cervical Plate System (K231460)

Substantial Equivalence: The Statera-C™ Spinal System is identical to the predicate device and is as safe and effective as the Globus Medical – ELLIPSE® and PROTEX® CT Spinal Systems. The Subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. There are no technological differences between the Subject device and its predicate devices. Thus, the Statera-C™ Spinal System is substantially equivalent to the predicate.

Conclusion: The Statera-C™ Spinal System have the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device. Thus, the subject device is substantially equivalent to the predicate devices.