K&J Consulting Corp.
Jeena Mathai
4027 Runnymeade Drive
Collegeville, Pennsylvania 19426

October 24, 2023

Re: K232586
Trade/Device Name: Rexious Spinal Fixation System, Statera™ Spinal Fixation System, Statera-M™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: August 23, 2023
Received: August 25, 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.10.24 14:34:37 -04'00'

for

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)*
K232586

Device Name
Rexious Spinal Fixation System, Statera™ Spinal Fixation System, Statera-M™ Spinal Fixation System

Indications for Use *(Describe)*
The Rexious Spinal Fixation System, Statera™ Spinal Fixation System, and Statera-M™ Spinal Fixation System are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion
(pseudarthrosis).

When used for posterior non-cervical screw fixation in pediatric patients, the Rexious Spinal Fixation System, Statera™ Spinal Fixation System, and Statera-M™ Spinal Fixation System are indicated as an adjunct to fusion to treat: adolescent idiopathic scoliosis, progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including infantile and juvenile idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, spondylolisthesis, spondylolysis, pseudarthrosis, failed prior fusion, and fracture caused by tumor and/or trauma in pediatric patients.
Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

When used as an anterolateral thoracolumbar system, the Rexious Spinal Fixation System, Statera™ Spinal Fixation System, and Statera-M™ Spinal Fixation System are intended for anterolateral screw (with staples) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

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.

510(k) SUMMARY

K&J Consulting
Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ 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:	August 23, 2023
Device Name:	Rexious Spinal Fixation System Statera™ Spinal Fixation System Statera-M™ Spinal Fixation System
Common Name:	Pedicle Screw Spinal Fixation System
Classification Name:	Thoracolumbosacral Pedicle Screw System Spinal Intervertebral Body Fixation Orthosis Spinal Interlaminal Fixation Orthosis
Classification Number:	21 CFR 888.3070 21 CFR 888.3060 21 CFR 888.3050
Product Code/ Classification:	NKB, KWP, KWQ, class II
Device Description:	The Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System are top-loading multiple component, posterior spinal fixation systems which consist of pedicle screws, rods, set screws, connectors, hooks, washers, staples, and transverse (cross) linking mechanisms. The Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The implant components are supplied non-sterile, single use and fabricated from titanium or titanium alloy (Ti-6Al-4V ELI) as specified in ASTM F67, F136, and F1295 and from Cobalt-Chromium-Molybdenum (CoCr) as specified in ASTM F1537. Various sizes of these implants are available.
Indications for Use:	The Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in

the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

When used for posterior non-cervical screw fixation in pediatric patients, the Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System are indicated as an adjunct to fusion to treat: adolescent idiopathic scoliosis, progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including infantile and juvenile idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, spondylolisthesis, spondylolysis, pseudarthrosis, failed prior fusion, and fracture caused by tumor and/or trauma in pediatric patients.

Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

When used as an anterolateral thoracolumbar system, the Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System are intended for anterolateral screw (with staples) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Performance Data: Non-clinical testing was performed to demonstrate that the subject Statera™ Spinal System, and Statera-M™ Spinal System are 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™ Spinal System, and Statera-M™ Spinal System are substantially equivalent to the legally marketed predicate devices.
For the remaining subject devices, submission is only transferring name of a system that has already been cleared under K222415. As those subject devices are identical to the predicate devices, no performance testing is required.

Predicate Device: Primary predicate:
Dio Medical - Rexious Spinal Fixation System (K222415)

Additional predicates:
Globus Medical – Revere Stabilization System (K133350)

Substantial Equivalence:	The Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System are substantially equivalent to the predicate device, the Dio Medical - Rexious Spinal Fixation System. 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 Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System are substantially equivalent to the predicates.
Conclusion:	The Rexious Spinal Fixation System, Statera™ Spinal System, and Statera-M™ Spinal System have the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. Thus, the subject devices are substantially equivalent to the predicate devices.