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

December 13, 2023

Re: K232877
Trade/Device Name: FaSet Fixation System, UNITY Sacroiliac Joint Fixation System, Huvex Interspinous Fixation System, and AEON-C™ Stand Alone System
Regulatory Class: Unclassified
Product Code: MRW, OUR, HWC, PEK, OVE, ODP
Dated: September 14, 2023
Received: September 15, 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: 2023.12.13 09:16:28 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K232877

Device Name
FaSet Fixation System

Indications for Use *(Describe)*
The FaSet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of facet joints. The Facet Screw System is indicated for posterior surgical treatment with or without bone graft at single or multiple levels from C2 to S1 (inclusive). For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The FaSet Fixation System is indicated for treatment for any or all of the following:
- Spondylolisthesis
- Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity
- Spondylolysis
- Degenerative Disk Disease (DDD) as defined by back pain of discogenic origin with degeneration of disk confirmed by history and radiographic studies and/or degenerative disease of the facets with instability
- Trauma including spinal fractures and/or dislocations.

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.

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)*
K232877

Device Name
UNITY Sacroiliac Joint Fixation System

Indications for Use *(Describe)*

The UNITY Sacroiliac Joint Fixation System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including degenerative sacroiliitis and sacroiliac joint disruptions
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion

The UNITY Sacroiliac Joint Fixation System is also indicated for fracture fixation of acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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)

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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)*
K232877

Device Name
Huvex Interspinous Fixation System

Indications for Use *(Describe)*
The Huvex Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device intended for use in the lumbar spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), tumor, and/or lumbar spinal stenosis. The Huvex Interspinous Fixation System is intended for use, in conjunction with autogenous bone graft, and not intended for stand-alone use.

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)

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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)*
K232877

Device Name
AEON-C™ Stand Alone System

Indications for Use *(Describe)*
The AEON-C™ Stand Alone System is a stand-alone anterior cervical intervertebral fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The AEON-C™ Stand Alone System should be packed with autograft and/or allograft comprised of cancellous, cortical and/or corticocancellous bone graft and implanted with an anterior approach. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device. If the device is being used without the provided screws, supplemental fixation must be used.

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)

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510(k) SUMMARY

FaSet Fixation System, UNITY Sacroiliac Joint Fixation System, Huvex Interspinous Fixation System, and AEON-C™ Stand Alone System

Submitter: K&J Consulting Corp.
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Date Prepared: November 13, 2023

Device Names:	FaSet Fixation System	UNITY Sacroiliac Joint Fixation Systems	Huvex Interspinous Fixation System	AEON-C™ Stand Alone System
Common Name:	System, Facet Screw Spinal Device	Sacroiliac Joint Fixation Screw	Spinous Process Plate	Intervertebral Body Fusion Device
Classification Name:	Unclassified	Smooth or threaded metallic bone fixation fastener	Spinal interlaminal fixation orthosis	Intervertebral body fusion device
Regulation Number:	Unclassified	21 CFR 888.3040	21 CFR 888.3050	21 CFR 888.3080
Product Code:	MRW	OUR, HWC	PEK	OVE, ODP
Classification	Unclassified	Class II	Class II	Class II

Description: The purpose of this submission is to transfer the names of previously cleared systems, edit the indications for use, and add new components to the UNITY Sacroiliac Joint Fixation System.

The FaSet Fixation System consist of permanent implant devices manufactured from titanium or titanium alloy (Ti-6Al-4V ELI) as specified in ASTM F67, and F136. Various sizes and lengths of these implants are available to accommodate patient anatomy. The device is intended to provide mechanical support and stability to the implanted

level until biologic fusion is achieved.

The UNITY Sacroiliac Joint Fixation System consists of screws designed to enhance sacroiliac joint fusion. The UNITY Sacroiliac Joint Fixation System is offered in various diameters, lengths, and three screw types in cannulated form to accommodate patient anatomy and is manufactured from titanium alloy (Ti-6Al-4V ELI) as specified in ASTM F136 and cobalt chrome alloy as specified in ASTM F1537. The three design types of the subject device are:

1. Standard Thread Screw (with and without slots)
2. Lag Screw (with and without slots) and
3. Washer Screw (with slots)

The Huvex Interspinous Fixation System consists of a left plate, a right plate, pin, bolt, inner cap, center bar, and set screw. Each of these components is provided in several sizes to allow for the construction of five different HUVEX Interspinous Fusion implant sizes. The left plate is provided assembled with the poly axial bar. The bar has a bone graft window to allow fusion between spinous process. Poly axial bar is also designed to fit the anatomical characteristics of the spinous process. The right plate is designed to be combined with left plate fixed to spinous process. Right plate contains a set screw to lock the right plate to the poly axial bar. The Huvex Interspinous Fixation System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F136.

In addition to the implants a set of reusable surgical instruments are provided. Both implant and instruments have trays that are used for handling and storage.

The AEON-C™ Stand Alone System includes PEEK interbodies and titanium interbodies, which utilize a titanium alloy locking mechanism that is either integrated in an anterior fixation plate or within the interbody. Both PEEK interbodies and titanium interbodies, with or without fixation plates, are to be anchored to patient anatomy via two (2) titanium alloy bone screws. The implant design includes multiple footprints, heights and lordosis options and the screw design includes multiple diameters and lengths, to fit a variety of patient anatomies. The interbodies can be used without the provided screws when supplemental fixation is used.

Indications for Use:

The FaSet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of facet joints. The Facet Screw System is indicated for posterior surgical treatment with or without bone graft at single or multiple levels from C2 to S1 (inclusive). For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly

through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The FaSet Fixation System is indicated for treatment for any or all of the following:

- Spondylolisthesis
- Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity
- Spondylolysis
- Degenerative Disk Disease (DDD) as defined by back pain of discogenic origin with degeneration of disk confirmed by history and radiographic studies and/or degenerative disease of the facets with instability
- Trauma including spinal fractures and/or dislocations.

The UNITY Sacroiliac Joint Fixation System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including degenerative sacroiliitis and sacroiliac joint disruptions
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion

The UNITY Sacroiliac Joint Fixation System is also indicated for fracture fixation of acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

The Huvex Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device intended for use in the lumbar spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), tumor, and/or lumbar spinal stenosis. The Huvex Interspinous Fixation System is intended for use, in conjunction with autogenous bone graft, and not intended for stand-alone use.

The AEON-C™ Stand Alone System is a stand-alone anterior cervical intervertebral fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The AEON-C™ Stand Alone System should be packed with autograft and/or allograft comprised of cancellous, cortical and/or corticocancellous bone graft and implanted

	with an anterior approach. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device. If the device is being used without the provided screws, supplemental fixation must be used.
Predicate Device:	Primary Predicate: FaSet Fixation System (K222515)- Huvexel Co. Ltd. Additional predicates: UNITY Sacroiliac Joint Fixation System (K222448) - Huvexel Co. Ltd., Huvex Interspinous Fixation System (K223790) - Huvexel Co. Ltd., and AEON-C™ Stand Alone System (K223140) - Huvexel Co. Ltd.
Substantial Equivalence:	The K&J Consulting - FaSet Fixation System, Huvex Interspinous Fixation System, and AEON-C™ Stand Alone System are identical to the predicate devices and are substantially equivalent to the Dio Medical - FaSet Fixation System, Huvex Interspinous Fixation System, and AEON-C Stand Alone System. New components are being added to the UNITY Sacroiliac Joint Fixation System, but the components have similar technological characteristics to previously cleared system components. The Subject devices have the same intended uses and similar indications, technological characteristics, and principles of operation as their predicate devices. There are no technological differences between the Subject device and their predicate devices resulting in no new issues of safety or effectiveness. Thus, the K&J Consulting - FaSet Fixation System, UNITY Sacroiliac Joint Fixation System, Huvex Interspinous Fixation System, and AEON-C™ Stand Alone System are substantially equivalent to the predicates.
Performance Data:	The K&J Consulting - FaSet Fixation System, Huvex Interspinous Fixation System, and AEON-C™ Stand Alone System devices are identical to predicate devices and therefore, no performance testing is required. New components being added to the UNITY Sacroiliac Joint Fixation System, but the new components do not introduce a new mechanical worst-case, so no new testing is required.
Conclusion:	The K&J Consulting- FaSet Fixation System, UNITY Sacroiliac Joint Fixation System, Huvex Interspinous Fixation System, and AEON-C™ Stand Alone System have the same intended uses and similar indications, technological characteristics, and principles of operation as their predicate device. Thus, the subject devices are substantially equivalent to the predicate devices.