April 19, 2021

Medynus Inc.
℅ Jeena Mathai
President
Eerkie Corporation
4027 Runnymeade Drive
Collegeville, Pennsylvania 19426

Re: K210420
Trade/Device Name: Goblin and Goblin LS Pedicle Screw Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: February 22, 2021
Received: February 23, 2021

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 (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, 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)*
K210420

Device Name
Goblin and Goblin LS Pedicle Screw Systems

Indications for Use *(Describe)*
The Goblin and Goblin LS Pedicle Screw Systems are intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications:

- 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);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis and/or lordosis);
- Tumor and pseudarthrosis

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

Medynus's
Goblin and Goblin LS Pedicle Screw Systems

Sponsor:	Manufacturer	Medynus Inc 18 Technology Dr. Ste 109 Irvine, CA 92618
	Official Contact	David Shin
	Phone:	9499320847
	Fax:	9499320851
	Contact Person	Jeena Mathai mgsharemg@gmail.com
	Date:	April 19, 2021

Device Name:	Goblin and Goblin LS Pedicle Screw Systems
Common Name:	Pedicle Screw Spinal Fixation System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification Number:	21 CFR 888.3070
Product Code/Classification:	NKB, class II

Description:

The Goblin and Goblin LS Pedicle Screw Systems are top-loading multiple component, posterior spinal fixation systems which consist of pedicle screws, rods, set screws, connectors, and transverse (cross) linking mechanisms. The implant components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) as specified in ASTM F136. Various sizes of these implants are available.

Indications For Use:

The Goblin and Goblin LS Pedicle Screw Systems are intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications:

- 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);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis and/or lordosis);
- Tumor and pseudarthrosis

Performance Data:	Non-clinical testing was performed to demonstrate that the subject Goblin and Goblin LS Pedicle Screw Systems are substantially equivalent to the predicate device. The following testing was performed in accordance with the ASTM F1717: - Static compression - Dynamic compression - Static Torsion The nonclinical tests demonstrate that the Goblin and Goblin LS Pedicle Screw Systems are as safe, as effective, and performs as well as or better than the legally marketed predicate devices.
Predicate Device:	Primary predicate: Globus Medical – REVERE Stabilization System (K061202 and K093294) Additional predicates: Huvexel – Rexious Spinal Fixation System (K111362 and K173131) and CG Bio. Co. Ltd.- LumFix Spinal Fixation System (K160731).
Reference Devices:	K171808 - TDM Small Locking Plate and Screw System K190830 - TDM Screw System
Technological Characteristics	The Goblin and Goblin LS Pedicle Screw Systems were shown to be substantially equivalent and have equivalent technological characteristics to its predicate and reference devices through comparison in areas including design, labeling/intended use, material composition, function, range of sizes, and packaging.
Performance and SE Determination:	The Goblin and Goblin LS Pedicle Screw Systems have been demonstrated to be substantially equivalent to the predicate system(s) with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device(s).