January 11, 2021

GetSet Surgical, SA
% Carolyn Guthrie
Director of Regulatory & Quality
Kapstone Medical, LLC
520 Elliot St.
Charlotte, North Carolina 28202

Re: K202505
Trade/Device Name: GetSet Surgical GoPLF! Posterior Lateral Fusion System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: January 6, 2021
Received: January 7, 2021

Dear Carolyn Guthrie:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202505

Device Name
GetSet Surgical GoPLF! Posterior Lateral Fusion System

Indications for Use *(Describe)*

The GetSet Surgical GoPLF! Posterior Lateral Fusion System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following: degenerative disc disease (DDD; 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; tumor; pseudoarthrosis; and failed previous fusion.
The GoPLF! Posterior Lateral Fusion System is for prescription use only and is to be used in an open, posterior approach, and can be used with autograft and/or allograft.

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

1. Date of Preparation:

November 17, 2020

2. Applicant

GetSet Surgical, SA
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1066 Epalinges
Switzerland
Contact: Ole Stoklund, CEO
Phone: +31 733035535.

3. Official Correspondent

Kapstone Medical LLC
520 Elliot St.
Charlotte, NC 28202

4. Contact Person:

Carolyn Guthrie
Email: cguthrie@kapstonemedical.com
Phone: +1 704-737-2866

5. Device Name

Trade Name: GetSet Surgical GoPLF! Posterior Lateral Fusion System
Common Name: Pedicle Screw System
Regulation Description: Thoracolumbosacral Pedicle Screw System
Regulations Number: 21 CFR 888.3070
Product Code: NKB
Classification: Class II
Panel: Orthopedic

6. Primary Predicate Device

Medtronic CD HORIZON® Spinal System (K090390)

7. Indications for Use:

The GetSet Surgical GoPLF! Posterior Lateral Fusion System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following: degenerative disc disease (DDD; 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; tumor; pseudoarthrosis; and failed previous fusion.

The GoPLF! Posterior Lateral Fusion System is for prescription use only and is to be used in an open, posterior approach and can be used with autograft and/or allograft.

8. Device Description

8.1 Product Names

GetSet Surgical (GetSet) GoPLF! Posterior Lateral Fusion System (Pedicle screws, rods, and instruments)

8.2 Intended Performance

The GetSet Surgical GoPLF! Posterior Lateral Fusion System is offered sterile and consists of implants and instruments.

The GoPLF! Posterior Lateral Fusion System Implants consist of a variety of sizes of pedicle screws, and rods designed to provide immobilization and stabilization of spinal segments as an adjunct to fusion in skeletally mature patients. The pedicle screws are intended to be inserted bilaterally into the pedicles of each vertebral segment, connected with the rod, and intended for spinal fusion at the selected level. The system conforms to patient anatomy for placement in the thoracolumbar human spine and for iliosacral fixation.

The GoPLF! Posterior Lateral Fusion System is offered with GetSet GoPLF! general and system-specific instruments as accessories. The method of use of the instruments is provided in the Surgical Technique Guide.

9. Technological Characteristics

As was established in this submission, the subject device GoPLF! Posterior Lateral Fusion System is substantially equivalent to the predicate device, cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device through comparison in areas including design, intended use, material composition, function and sterilization method.

10. Performance Data

There are no clinical data generated and held by the manufacturer, i.e., no pre-marketing or post-market clinical studies or animal studies have been performed. The following information is provided in support of substantial equivalence.

10.1 Biocompatibility

The subject device GoPLF! Posterior Lateral Fusion System is classified as an implant device with tissue/bone contact and permanent contact. Therefore, according to ISO 10993-1 the biological evaluation was assessed for potential effects. The GetSet Surgical GoPLF! Posterior Lateral Fusion devices are manufactured from Ti-6AI-4V ELI conforming to ASTM standard F136. The evaluation was based on product-specific tests and on published literature data. The results show that implants made of Ti-6AI-4V ELI have a high demonstrable biological safety. No concerns arose that would preclude clinical use of GoPLF! Posterior Lateral Fusion System. The instruments are classified as externally communicating medical devices with tissue/bone contact and less than 24 hours contact. All used materials have a medical grade. The requirements of the ISO 10993 standard are fulfilled.

10.2 Pyrogenicity / Endotoxin Testing

The bacterial endotoxin test was performed utilizing worst case subject implants to verify that the subject implants meet the acceptance criteria of ≤ 20 EU/kit. Testing was successfully performed, and it was confirmed that the GoPLF! Posterior Lateral Fusion System meets the acceptance criteria of ≤ 20 EU/kit according to USP, General Chapter <85>, Bacterial Endotoxins Test, and EP Ch 2.6.14 Bacterial Endotoxins as recommended in ISO 10993-11:2009 Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.

10.3 Mechanical Testing

To demonstrate equivalence to the predicate device, the CD HORIZON® Spinal System, testing was performed according to ASTM F1717-15, “Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model”. The GoPLF! Pedicle Screw System is geometrically and mechanically equivalent to the predicate device.

10.4 Magnetic Resonance Safety Testing

Nonclinical testing has demonstrated that the GetSet Surgical GoPLF! Posterior Lateral Fusion Device range is “MR Conditional” in accordance with the ASTM F2503-20 standard definitions.

11 Conclusion

The GoPLF! Posterior Lateral Fusion System and the predicate device Medtronic CD HORIZON® Spinal System (K090390) have the same “Indications for Use,” are available by prescription only, and are provided sterile. Any technical differences, which were identified, do not result in new questions of safety or effectiveness.

Through assessment of technological characteristics, indications for use and performance data, it can be concluded that GoPLF! Posterior Lateral Fusion System is is substantially equivalent to the CD HORIZON® Spinal System.