March 21, 2025

GetSet Surgical, SA
℅ Christine Scifert
Partner
MRC Global
9085 East Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K250186
Trade/Device Name: GoLIF! Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 16, 2025
Received: January 22, 2025

Dear Christine Scifert:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250186

Device Name

GoLIF! Lumbar Interbody Fusion System

Indications for Use *(Describe)*

The GetSet GoLIF! Lumbar Interbody Fusion (IBF) system is indicated for interbody fusion with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft in patients with symptomatic Degenerative Disc Disease (DDD) at either one or two contiguous levels in the lumbar spine, from L1-L2 to L5-S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via a transforaminal approach. These devices are intended to be used with supplemental posterior fixation, which has been cleared by the FDA for use in the lumbar spine.

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

GoLIF! Lumbar Interbody Fusion System
January 21, 2025

Company: GetSet Surgical SA
Route de la Corniche 4
1066 Epalinges
Switzerland

Primary Contact: Christine Scifert – Partner
MRC Global
9085 E. Mineral Cir., Suite 110
Centennial, CO 80112
Phone: (901) 831-8053
Email: christine.scifert@AskMRCGlobal.com

Company/Secondary Contact: Jowita Sokalska
Quality and Regulatory Manager
GetSet Surgical SA
Phone: +48 605044 250
js@getsetsurgical.com

Trade Name: GoLIF! Lumbar Interbody Fusion System

Common Name: Intervertebral Fusion Device with Bone Graft , Lumbar

Classification: Class II

Regulation: 21 CFR 888.3080 (Intervertebral Fusion Device With Bone Graft, Lumbar)

Panel: Orthopedic

Product Code: MAX

Primary Predicate: Nuvasive CoRoent Lumbar System (Large Platform) – K151472

Device Description:

The GoLIF! Lumbar Interbody Fusion System are sterile implantable cages and sterile instruments intended to be inserted into the intervertebral body space of the lumbosacral spine and intended for intervertebral body fusion. The GetSet GoLIF! implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column.
The implants are designed for a unilateral posterior transforaminal (TLIF) approach or posterior lumbar interbody fusion (PLIF) approach. It is specially designed for small incision (minimally invasive), resulting

in a relatively atraumatic operation for the patient. Implants, used with supplemental fixation and bone graft, provide improved stability, height restoration and lordosis to optimize fusion.
Based on anatomical reasons, implants will be offered in lengths of 22mm and 26mm, heights of 8-14mm in 1mm increments, and at a width of 10mm. The implant has a tapered tip to allow distraction upon insertion, and teeth on the superior and inferior surfaces help the implant to resist expulsion and to resist implant migration. The dome shape allows for 7-18 degree lordosis when placed at a TLIF Oblique or PLIF position whilst maintaining coronal alignment due to the neutral region in the mid-section of the implant when positioned in a lateral position. The openings allow for packing of bone graft.

The GoLIF! Lumbar Interbody Fusion System also includes instruments to facilitate implantation of the subject implant devices. Instruments are manufactured from Polyacrylamide (IXEF), Polybutylene terephthalate (PBT), and medical grade stainless steel.

The GoLIF! Lumbar Interbody Fusion System was the subject of two previously withdrawn submissions – K201409 and K230368. During the course of review for both of those submissions, the Agency requested additional information. All changes provided to FDA in previous responses to AI and interactive questions have been embedded in the subject submission and the outstanding questions that remained regarding packaging and biocompatibility are addressed in those corresponding sections.

Indications for Use:

The GetSet GoLIF! Lumbar Interbody Fusion (IBF) system is indicated for interbody fusion with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft in patients with symptomatic Degenerative Disc Disease (DDD) at either one or two contiguous levels in the lumbar spine, from L1-L2 to L5-S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via a transforaminal approach. These devices are intended to be used with supplemental posterior fixation, which has been cleared by the FDA for use in the lumbar spine.

Substantial Equivalence:

The subject GoLIF! Lumbar Interbody Fusion System is substantially equivalent to the following predicate devices:

Primary Predicate:

- NuVasive CoRoent® Lumbar System (Large Platform) – K151472

The subject device GoLIF! Lumbar Interbody Fusion System was shown to be substantially equivalent and have the same technological characteristics to the previously FDA cleared predicate device through comparison in areas including design, intended use, material composition, function, and sterilization method. Any technical differences, which were identified and discussed in this submission, do not result in new questions of safety or effectiveness.

Performance Testing:

Mechanical testing, including static and dynamic axial compression and static and dynamic compression shear per ASTM F2077, as well as subsidence per ASTM F2267 and expulsion have been performed on the subject GoLIF! Interbody Fusion System devices and the results have shown them to be substantially equivalent to the predicate interbody devices. Limulus Amebocyte Lysate (LAL) testing was was conducted in accordance with ANSI/AAMI ST72 to confirm the device does not exceed the limit of 20 EU per device and all samples met acceptance criteria.

Conclusion:

Based on the performance analysis and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.