October 7, 2024

Retropsoas Technologies, LLC
℅ Jeffrey Brittan
Vice President of Product Realization
SpiTrex 3D (Watershed Idea Foundry, Inc. dba SpiTrex 3D)
1815 Aston Ave., Ste 106
Carlsbad, California 92008

Re: K242457
Trade/Device Name: EARP Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 16, 2024
Received: August 19, 2024

Dear Mr. Brittan:

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,

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)*

K242457

Device Name

EARP Interbody System

Indications for Use *(Describe)*

The EARP Interbody System is intended for intervertebral body fusion in the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 of the lumbosacral spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone to facilitate fusion and are implanted via a posterolateral approach.

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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K242457
510(k) Summary

Applicant	Retropsoas Technologies, LLC 34 Countryside Lane Frontenac, MO 63131 USA Telephone: 618-402-0035 Contact: Dr. Nicholas Poulos, CEO Email: npoulos@retropsoas.com
Correspondent	Jeffrey Brittan Vice President of Product Realization SpiTrex 3D (Watershed Idea Foundry, Inc. dba SpiTrex 3D) Telephone: 714-287-6780 Email: jeffbrittan@spitrexorthopedics.com

DEVICE NAME

Device Trade Name	EARP Interbody System
Common Name	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification Name	Intervertebral body fusion device
Regulation Number	21 CFR 888.3080
Product Code	MAX

LEGALLY MARKETED PREDICATE DEVICES

Predicate #	K212477
Predicate Trade Name	EARP Interbody System
Product Code	MAX

Predicate #	K193645
Predicate Trade Name	nva, nvp, and nvt
Product Code	MAX

DEVICE DESCRIPTION SUMMARY

The EARP Interbody System is an intervertebral body fusion device used in the lumbar spine following discectomy. All devices are manufactured from PEEK OPTIMA® LT1 per ASTM F2026 and include tantalum markers per ASTM F560 for radio-graphic visualization.

The devices have multiple footprints to adapt to the general shape of the vertebral endplates and have a hollow center to accommodate bone graft. Each footprint is available in multiple heights to accommodate patient variability and there are anti-migration features on the superior and inferior surfaces designed to improve fixation, stability, and prevent back out and migration.

INTENDED USE / INDICATIONS FOR USE

The EARP Interbody System is intended for intervertebral body fusion in the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 of the lumbosacral spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone to facilitate fusion and are implanted via a posterolateral approach.

INDICATIONS FOR USE COMPARISON

The only modification to the Indications for Use for the subject device in comparison to the predicate device is to add text clarifying the option for use with allogenic bone graft. This update helps to further align wording regarding grafting with that of other recently cleared intervertebral body fusion devices with the same intended use; it does not alter device performance characteristics or the surgical technique used to implant the device, and the intended use of the subject device remains the same.

TECHNOLOGICAL COMPARISON

The subject device has been updated with 50mm width options and minor design updates that maintain equivalent design characteristics, materials, chemical composition, and principle of operation as the predicate devices.

NON-CLINICAL TESTS SUMMARY & CONCLUSIONS

Analysis of the subject device modifications verified that they would not impact function or performance. Results of this analysis demonstrated that the additional sizing options, as well as minor design updates to the spacer and inclusion of an additional tantalum marker, would not negatively impact mechanical strength, instrument mating, anatomic fit, bone grafting, or radiographic visualization. Accordingly, the analysis supported the conclusion that the subject EARP Interbody System is substantially equivalent to the predicates.