February, 4, 2023

Simparo, Inc.
Chris Harber
President
1125 Corporate Drive North
Mobile, Alabama 36607

Re: K222574
Trade/Device Name: Simparo Anchor Line Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 10, 2023
Received: January 11, 2023

Dear Chris Harber:

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,

Sara S. Thompson -S

For

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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)*

K222574

Device Name

Simparo Anchor Line Fixation System

Indications for Use *(Describe)*

Intended Use:

The Simparo Anchor Line Fixation System, when used for fixation of bone-to-bone or soft-tissue-to-bone, is intended as an anchor fixation system, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Indications for Use:

Specifically, the Simparo Anchor Line Fixation System is indicated for carpometacarpal (CMC) joint arthroplasty as an adjunct in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpals when the trapezium has been excised due to osteoarthritis.

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
SIMPARO ANCHOR LINE FIXATION SYSTEM

Company:	
Company Name	Simparo, Inc.
Company Address	1125 Corporate Drive North Mobile, AL. 36607
Primary Contact:	Chris Harber**,** President Simparo, Inc.
Company/Secondary Contact:	Penny Rasmussen
Trade Name:	Simparo Anchor Line Fixation System
Common Name:	Fastener, Fixation, Nondegradable. Soft Tissue
Classification:	Class II
Regulation Number:	21 CFR 888.3040
Panel:	Orthopedic
Product Code:	MBI

Device Description:

The Simparo Anchor Line Fixation System is a dual anchor construct used to provide stabilization of the thumb and index metacarpals for treatment of carpometacarpal (CMC) arthritis. The Anchor Line Fixation System consists of an index anchor (5mm) and a thumb anchor (5mm) connected by a single strand of #2 Teleflex Force Fiber nonabsorbable braided suture. This construct provides a suspension sling as a supportive device to maintain the thumb and index metacarpals in proper alignment during capsular healing, hematoma and scar tissue formation following a trapeziectomy (removal of the trapezium) for the treatment of thumb CMC osteoarthritis. The Anchor Line Fixation System is manufactured from titanium/titanium alloys, stainless steel and PEEK.

Intended Use:

The Simparo Anchor Line Fixation System, when used for fixation of bone-to-bone or soft-tissue-to-bone, is intended as an anchor fixation system, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Indications for Use:

Specifically, the Simparo Anchor Line Fixation System is indicated for carpometacarpal (CMC) joint arthroplasty as an adjunct in the suspension of the thumb metacarpal during the

healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpals when the trapezium has been excised due to osteoarthritis.

Substantial Equivalence

The subject Simparo Anchor Line Fixation System components are substantially equivalent with respect to the materials, design and indications for use to the following devices, previously cleared by the FDA:

Primary Predicate:

- Arthrex, Inc., CMC Mini TightRope, K140328

Secondary Predicate:

- Axya Medical, Inc., AxyaLoop Anchor (5mm), K060970

The subject components for the Simparo Anchor Line Fixation System are substantially similar to the Arthrex CMC Mini TightRope (K140328) except for size and suture type. There are no new issues related to the safety and effectiveness of the subject device. The Simparo Anchor Line Fixation System is substantially equivalent to the predicate device in indications for use, design, operational principles and materials. A secondary predicate, the AxyaLoop Anchor by Axya Medical, Inc., is included to address the differences in device size and suture type between the predicate and subject device.

The proposed subject device has the same intended use and similar technological characteristics to the predicate. Any differences do not raise new questions or safety and effectiveness, and the proposed device is at least as safe and effective as the legally marketed predicate device. The reference device, the AxyaLoop Anchor (5mm) cleared under K060970 is included because it is similar in technologic characteristics such as material (Titanium), size (5mm) and suture (Force Fiber) to the subject device.

Testing:

Bacterial Endotoxin Test:

The LAL endotoxin test (Limulus Amebocyte Lysate) Gel Clot method was used to test the products for the presence of endotoxins with an acceptance criteria of ≤ 20EU / device The test results showed that all samples passed the endotoxin testing.

Performance Testing:

Mechanical testing and engineering analyses were conducted to demonstrate the Simparo Anchor Line Fixation System and to demonstrate substantial equivalence to the predicate components.

CONCLUSION:

The subject device has the same or similar indications/ intended use as the predicates Arthrex CMC TightRope and Axya AxyaLoop. The subject device has similar technological characteristics to the predicates, and the performance data and analyses demonstrates that:

- Any differences do not raise new questions of safety and effectiveness; and
- The proposed subject device is at least as safe and effective as the legally marketed predicated devices.

Therefore, Simparo's conclusion from the comparison between the subject and predicates demonstrates that the Simparo Anchor Line Fixation System indications, intended use, design technology, similar medical grade materials, a comparable surgical technique, and with no new safety and efficacy risks is as effective and performs equivalent to the predicate devices.