January 26, 2023

Integrity Orthopaedics, Inc.
Jeff Sims
Vice President, Regulatory Affairs
5565 Pioneer Creek Drive
Maple Plain, Minnesota 55359

Re: K222589
Trade/Device Name: Flexible Suturing System with Anchors (FSSA)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 26, 2022
Received: December 27, 2022

Dear Jeff Sims:

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)*

K222589

Device Name

Flexible Suturing System with Anchors (FSSA)

Indications for Use *(Describe)*

The Flexible Suturing System with Anchors (FSSA) is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

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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INTEGRITY ORTHOPAEDICS
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510(k) Summary
Flexible Suturing System with Anchors (FSSA)

Applicant Information

Applicant Name:	Integrity Orthopaedics, Inc.
Applicant Address:	5565 Pioneer Creek Drive Maple Plain, MN 55359
Contact Person:	Jeff Sims Vice President, Regulatory Affairs
Telephone:	952-594-2795
e-mail:	jsims@integrity-ortho.com
Date Prepared:	January 26, 2023

Name of Device

Trade Name:	Flexible Suturing System with Anchors (FSSA)
Common Name:	Suture Anchors
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Proposed Class:	Class II
Product Code:	MBI
Regulation:	21 CFR Part 888.3040

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device:	ConMed Linvatec Soft Tissue to Bone System K091549
Company Name:	ConMed Linvatec

Description of the Device

The Flexible Suturing System with Anchors (FSSA) includes anchors, a pre-strung single common repair suture serially connecting the anchors in an array and an individual locking suture associated with each anchor (except the first anchor in the array) for selectively locking the repair suture relative to each anchor after tensioning the repair suture to form a tensioned stitch with a just prior implanted anchor in the array. The implanted array of anchors with a continuous set of anchor-to-anchor single suture stitches creates a seam-like attachment akin to a sewing machine construct. Each anchor of the FSSA is a monolithic injection molded body. An ancillary delivery instrument is utilized to create a bone hole and insert each anchor.

Indications for Use

The Flexible Suturing System with Anchors (FSSA) is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons or joint capsules to the bone.

The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

Summary Comparison of Technical Characteristics

The components of the FSSA and counterpart components of the predicate device perform the exact same functions. However, the way each function is accomplished (exact structure) varies slightly. The FSSA anchor has a monolithic generally cylindrical body that is inserted lengthwise below the cortical shell, then rotated to provide a retention surface in contact with the inner surface of the cortical shell and/or cancellous bone. In contrast, the predicate device includes expandable wings that extend from the anchor body when activated to provide a retention surface. However, each perform the same function with minor variation in structure. A lateral surface below the cortical shell provides retention of the anchor in both devices. Additionally, there is a difference in the structure of the mechanism for locking the repair suture relative to anchor. The FSSA locks the repair suture between anchors utilizing a locking suture. The predicate device includes an inner anchor member that can be moved to a locked position that pinches or locks the repair suture between the inner and outer anchor bodies to prevent relative movement.

Performance Data

Testing has been completed to demonstrate that the FSSA performs as intended and is substantially equivalent to the predicate device. The completed tests include standard verification and validation testing. Additionally, the following specific bench testing was completed for device comparisons: Suture Characterization, Insertion Testing, Pullout Testing, Fatigue Testing and Repair Suture Slippage Testing, as well as sterility assurance.

Conclusion

The substantial equivalence between the FSSA and the predicate device is confirmed by the results of extensive performance bench testing where it was shown that the varied features of the FSSA anchors perform as well or better as the corresponding features in the predicate device and therefore did not raise any safety and effectiveness concerns. Further, biocompatibility and sterility assurance results confirm all elements used in the flexible suturing system are safe, including permanent implantation materials of the anchor, repair suture and locking suture components. Therefore, the FSSA is substantially equivalent to the named predicate device.