September 23, 2020

Responsive Arthroscopy LLC
℅ Kristen Peña
Associate Manager, Product Development Operations
Cor Medical Ventures
215 S. Highway 101, Suite 200
Solana Beach, California 92075

Re: K202569
Trade/Device Name: Responsive Arthroscopy Interference Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: September 1, 2020
Received: September 4, 2020

Dear Ms. Peña:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202569

Device Name
Responsive Arthroscopy Interference Screw System

Indications for Use *(Describe)*

The Responsive Arthroscopy Interference Screws are intended to be used for fixation of tissue including ligament, tendon, soft tissue, or bone to bone. Interference fixation with PEEK or Titanium Interference Screws is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate. Specifically, screws are intended for use in the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction, Anterior Shoulder Instability

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfers in the Foot and Ankle, Bunionectomy

Knee: Anterior Cruciate Ligament Repair, Posterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal Joint

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

SUBMITTER:

Submitted By:

Company Name: Responsive Arthroscopy LLC
Address: 701 N. 3rd Street, Suite 208
Minneapolis, MN 55401
Telephone: 858-720-1847

CONTACT PERSON: Kristen Peña

DATE PREPARED: September 1, 2020

TRADE NAME: Responsive Arthroscopy Interference Screw System

COMMON NAME: Interference Screw System

CLASSIFICATION NAME: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

PRODUCT CODE: HWC, MBI

SUBSTANTIAL EQUIVALENCE:
The Responsive Arthroscopy Interference Screw System is substantially equivalent to the predicate device in all facets including: function, design, performance, material, and intended use.

Primary Predicate Device: Responsive Arthroscopy Interference Screw System (K180573)
Predicate Device: EZStart Interference Screw (K182955)

DEVICE DESCRIPTION:
The Responsive Arthroscopy Interference Screw System is a family of interference screws for the reattachment and fixation of tissue including ligament, tendon, soft tissue, or bone to bone. The system includes cannulated interference screws in both polyether ether ketone (PEEK) per ASTM F2026 and Ti-6Al-4V ELI titanium alloy per ASTM F136, along with drivers, sizers, reamers, taps, and guide wires for screw insertion.

The only design differences in the subject device are regarding interference screw length, cannulation, and driving feature. The screws are available in a variety of sizes to accommodate various procedures and patient anatomies. RA PEEK Interference Screws are offered with diameters from 7-12mm and lengths from 15-35mm. RA Titanium Interference Screws are offered with diameters from 7-10mm and lengths from 20-35mm.

The RA Interference Screw System implants are provided sterile. The RA Interference Screw System single-use instruments are provided sterile, and the RA Interference Screw System reusable instruments

are non-sterile and are to be sterilized by the end user. All RA Interference Screw implants and single-use instruments are sterilized with ethylene oxide (EO).

MATERIALS:
The RA PEEK Interference Screws are machined from extruded PEEK per ASTM F2026. The RA Titanium Interference Screws are machined from Ti-6Al-4V ELI titanium alloy per ASTM F136.

INDICATIONS FOR USE:
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Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal Joint

PERFORMANCE TESTING:
The following bench testing was performed on the Responsive Arthroscopy Interference Screw System**:**

Insertion (Driving) Torque
Static Push Out Force
Cyclic Pull Out Force
Bacterial Endotoxin Testing (LAL)

In summary, the performance testing of the Responsive Arthroscopy Interference Screw System indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSION:
The Responsive Arthroscopy Interference Screw System is substantially equivalent to a legally marketed predicate based on indications for use, technological characteristics, performance testing, and comparison to a predicate device.