September 9, 2020

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

Re: K202153
Trade/Device Name: Responsive Arthroscopy Knotless Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 31, 2020
Received: August 3, 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)*

K202153

Device Name
Responsive Arthroscopy Knotless Push-In Suture Anchors

Indications for Use *(Describe)*

The Responsive Arthroscopy Knotless Push-In Suture Anchors are intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, and elbow in the following procedures:

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

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy, Digital Tendon Transfers.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Vastus Medialis Obliquus Advancement, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.

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

Hip: Capsular Repair, Acetabular Labral Repair.

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

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

TRADE NAME: Responsive Arthroscopy Knotless Push-In Suture Anchors

COMMON NAME: Knotless Push-In Suture Anchor System

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

PRODUCT CODE: MBI

SUBSTANTIAL EQUIVALENCE:
The Responsive Arthroscopy Knotless Push-In Suture Anchor System is substantially equivalent to the predicate device in all facets including: function, design, performance, material, and intended use.

Primary Predicate Device:	Responsive Arthroscopy Suture Anchor System (K180951)
Reference Devices:	HS Fiber (Polyblend); RiverBond (Polyester); RiverSilk (Silk); RiverPro (Polypropylene); RiverLon (Nylon) (K100006)
	HS SutureTape (K153307)

DEVICE DESCRIPTION:
The Responsive Arthroscopy (RA) Knotless Push-In Suture Anchor System is an updated version of the RA Knotless Push-In Suture Anchor System previously cleared under K180951. The RA Knotless Push-In Suture Anchor is intended for fixation of suture (soft tissue) to bone. The system includes a variety of anchors made of polyetheretherketone per ASTM F2026 (PEEK) along with repair suture or suture tape, inserters, drills, broaches, and guides.

The only differences in the subject device are regarding suture geometry, anchor body geometry, and internal screw geometry. The RA Knotless Push-In Suture Anchor System anchors are available in a variety of geometries and configurations to accommodate various procedures and patient anatomies. RA Knotless Push-In Suture Anchor System anchors range in diameter from 3.5mm to 4.75mm and are either pre-loaded with or accept #2 suture or 2.5mm suture tape.

The RA Knotless Push-In Suture Anchor System anchors are pre-loaded on inserters and provided sterilized with ethylene oxide. The RA Knotless Push-In Suture Anchor System reusable instruments are non-sterile and are to be sterilized by the end user.

MATERIALS:
The Responsive Arthroscopy Knotless Push-In Suture Anchor System anchors are machined from extruded PEEK per ASTM F2026. Implantable repair sutures are either Riverpoint Medical #2 HS Fiber ultra-high molecular weight polyethylene suture previously cleared under K100006 or Riverpoint Medical ultra-high molecular weight polyethylene HS SutureTape previously cleared under K153307.

INDICATIONS FOR USE:
The Responsive Arthroscopy Knotless Push-In Suture Anchors are intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, and elbow in the following procedures:

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

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy, Digital Tendon Transfers.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Vastus Medialis Obliquus Advancement, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.

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

Hip: Capsular Repair, Acetabular Labral Repair.

PERFORMANCE TESTING:
The following bench testing was performed on the Responsive Arthroscopy Knotless Push-In Suture Anchor System**:**

Insertion Force Testing
Static & Cyclic Pullout Force Testing
Suture Locking Force Testing
Suture Characterization (previously cleared device reference)
Biocompatibility Risk Assessment
Bacterial Endotoxin Risk Assessment
Sterilization, Cleaning, and Shelf-Life Adoptions

In summary, mechanical testing of the Responsive Arthroscopy Knotless Push-In Suture Anchor System indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSION:
The Responsive Arthroscopy Knotless Push-In Suture Anchor System is substantially equivalent to a legally marketed predicate based on indications for use, technological characteristics, performance testing, and comparison to a predicate device.