January 3, 2019

Responsive Arthroscopy LLC
% Benjamin Arnold
Managing Member
Cor Medical Ventures LLC
215 S. Highway 101, Suite 200
Solana Beach, California 92075

Re: K180951
Trade/Device Name: Responsive Arthroscopy 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: November 8, 2018
Received: November 9, 2018

Dear Mr. Arnold:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180951

Device Name
Responsive Arthroscopy Large Screw-In Suture Anchors

Indications for Use *(Describe)*
The Responsive Arthroscopy Large Screw-In Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, 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.

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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)*
K180951

Device Name
Responsive Arthroscopy Large Push-In Suture Anchors

Indications for Use *(Describe)*
The Responsive Arthroscopy Large Push-In Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, 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.

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.

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)

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Indications for Use

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180951

Device Name
Responsive Arthroscopy Small Push-In Suture Anchors

Indications for Use *(Describe)*
The Responsive Arthroscopy Small Push-In Suture Anchors are intended to be used for fixation of 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, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for all Digits, Digital Tendon Transfers.

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)

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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)*
K180951

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 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)

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510(K) SUMMARY

SUBMITTER:

Submitted By:

Company Name: Responsive Arthroscopy LLC
Address: 701 N. 3rd Street, Suite 202
Minneapolis, MN 55401
Telephone: 858-720-1847

CONTACT PERSON: Benjamin Arnold

DATE PREPARED: April 09, 2018

TRADE NAME: Responsive Arthroscopy Suture Anchor System

COMMON NAME: Suture Anchor System

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

PRODUCT CODE: MBI

PREDICATE DEVICES:
The Responsive Arthroscopy (RA) Suture Anchor System is substantially equivalent to the predicate devices in all facets including: function, design, performance, material, and intended use.

Primary Predicate Device: Arthrex PushLock Anchors: K101679

Additional Predicate Devices: Arthrex Corkscrew Suture Anchors: K143745
Smith & Nephew TWINFIX Ultra PK Suture Anchors: K112526
Smith & Nephew FOOTPRINT Ultra PK Suture Anchors: K113274
ArthroCare MultiFIX S Ultra Knotless Fixation System: K131182
Arthrex SutureTak Suture Anchors: K140855
Arthrex Knotless SutureTak Suture Anchor: K171020
ConMed Linvatec NANO Suture Anchor: K112965
Smith & Nephew BIORAPTOR Knotless Suture Anchor: K121018
Arthrex Micro Corkscrew FT: K112237

DEVICE DESCRIPTION:
The Responsive Arthroscopy (RA) Suture Anchor System is a family of suture anchors for the fixation of soft tissue to bone. The system includes a variety of suture anchors made of polyether ether ketone per ASTM F2026 (PEEK) along with repair sutures, inserters, taps, punches, drills, and guide tubes.

The suture anchors are available in a variety of geometries and configurations to accommodate various procedures and patient anatomies. RA Suture Anchors range in diameter from 2.5mm to 5.5mm and are either pre-loaded with or accept #2 suture.

The RA Suture Anchor System implants are pre-loaded on inserters and provided sterile, RA Suture Anchor System single-use instruments are provided sterile, and the RA Suture Anchor System reusable instruments are non-sterile and are to be sterilized by the end user. All RA Suture Anchor System implants and single-use instruments are sterilized with ethylene oxide (EO).

MATERIALS:
The RA Suture Anchor System anchors are machined from extruded PEEK per ASTM F2026. Implantable repair sutures are Riverpoint Medical #2 HS Fiber ultra high molecular weight polyethylene suture, previously cleared under K100006.

INDICATIONS FOR USE:
The Responsive Arthroscopy Large Screw-In Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, 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.

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.

The Responsive Arthroscopy Large Push-In Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, 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.

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.

The Responsive Arthroscopy Small Push-In Suture Anchors are intended to be used for fixation of 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, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for all Digits, Digital Tendon Transfers.

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

Hip: Capsular Repair, Acetabular Labral Repair.

The Responsive Arthroscopy Knotless Push-In Suture Anchors are intended to be used for fixation of 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.

TECHNOLOGICAL CHARACTERISTICS:
The Responsive Arthroscopy Suture Anchor System devices are made from similar anchor and suture materials and have identical diameters, similar lengths, similar fixation grooves and/or threads, identical numbers of sutures, and similar insertion method to the predicate devices. Any differences between the Responsive Arthroscopy Suture Anchor System devices and the predicates are considered minor and do not raise questions concerning safety or effectiveness.

PERFORMANCE TESTING:
The following bench testing was performed on the Responsive Arthroscopy Suture Anchor System and predicate devices**:**

Suture Characterization (previously cleared device reference)
Insertion Torque Testing
Insertion Force Testing
Static & Fatigue Pullout Force Testing
Suture Locking Force Testing

Bacterial endotoxin testing was completed and met acceptable endotoxin limits per ANSI/AAMI ST72:2011(R2016). Mechanical testing of the Responsive Arthroscopy Suture Anchor System indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSIONS:
The Responsive Arthroscopy Suture Anchor System has shown to be substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing, and comparison to predicate devices.