April 27, 2021

Responsive Arthroscopy LLC
% Benjamin Arnold
Cor Medical Ventures, Inc.
2010 Jimmy Durante Boulevard, Suite 200
Del Mar, California 92014

Re: K203121
Trade/Device Name: Responsive Arthroscopy Thunderbolt System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, JDR
Dated: October 15, 2020
Received: October 16, 2020

Dear Benjamin 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/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,

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)*

K203121

Device Name

Responsive Arthroscopy Thunderbolt System

Indications for Use *(Describe)*

The Responsive Arthroscopy Thunderbolt System is intended for soft tissue to bone fixation for the following indications:

Shoulder: Bankart lesion repair, SLAP lesion repairs, Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff tear repair, Biceps Tenodesis

Foot and Ankle: Medial/lateral repair and reconstruction, Mid-and forefoot repair, Hallux valgus reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair, Ankle Syndesmosis fixation (Syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures

Elbow: Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment

Knee: ACL/PCL repair/ reconstruction, ACL/PCL patellar bone-tendon-bone grafts, Double-Tunnel ACL reconstruction, Extracapsular repair: MCL, LCL, and posterior oblique ligament, Illiotibial band tenodesis, Patellar tendon repair, VMO advancement, Joint capsule closure

Hand and Wrist: Collateral ligament repair, Scapholunate ligament reconstruction, Tendon transfers in phalanx, Volar plate reconstruction

Hip: 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.

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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: Benjamin Arnold

DATE PREPARED: March 24, 2021

TRADE NAME: Responsive Arthroscopy Thunderbolt System

COMMON NAME: Suture-Button Implant

CLASSIFICATION NAMES: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Staple, Fixation, Bone (21 CFR 888.3030)

PRODUCT CODES: MBI and JDR

SUBSTANTIAL EQUIVALENCE:

The Responsive Arthroscopy Thunderbolt System is substantially equivalent to the predicate devices in all facets including: function, design, performance, material, and intended use.

Primary Predicate Device: Biomet ToggleLoc™ System (K130033)

Additional Predicate Devices: Arthrex TightRope™ (K043248)

DEVICE DESCRIPTION:

The Responsive Arthroscopy Thunderbolt System is a knotless system for the fixation of soft tissue to bone. The system includes a suture-button implant assembly made of Ti-6Al-4V ELI per ASTM F136 and ultra high molecular weight polyethylene, an implantable two holed plate made of Ti-6Al-4V ELI per ASTM F136, and instrumentation including drills and drivers. The implants and single-use instruments are provided sterile, and the reusable instruments are non-sterile and are to be sterilized by the end user.

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Hip: Acetabular labral repair

PERFORMANCE TESTING:

The following non-clinical testing was performed on the Responsive Arthroscopy Thunderbolt System:

- Static Pullout Force Testing
- Cyclic Pullout Force Testing
- Suture Characterization (previously cleared device reference)
- Biocompatibility Risk Analysis
- Sterility
- Packaging
- Shelf-Life
- Pyrogenicity

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

CONCLUSIONS:

The Responsive Arthroscopy Thunderbolt 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.