DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 13, 2017

Ziptek, LLC
% Janice Hogan
Partner
Hogan Lovells Us LLP
1835 Market Street
29th Floor
Philadelphia, Pennsylvania 19103

Re: K162429
Trade/Device Name: ZipE® Knotless Tissue Repair and Attachment Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI, KGS
Dated: February 10, 2017
Received: February 10, 2017

Dear Ms. Hogan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K162429

Device Name

ZipE® Knotless Tissue Repair and Attachment Devices

Indications for Use *(Describe)*

The **ZIPE® Knotless Tissue Repair and Attachment Devices** are intended for fixation of tissue to bone and tissue to tissue.
This product is intended for the following indications:

- *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, Midfoot Reconstruction, Metatarsal Ligament Repair
- *Knee:* Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair
- *Hand/Wrist:* Scapholunate Ligament Reconstruction, Ulnar and Radial Collateral Ligament Reconstruction
- *Elbow:* Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

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

ZIPE® Knotless Tissue Repair and Attachment Devices

Preparation Date: February 10, 2017

Applicant/Sponsor: Ziptek, LLC
1250 S Tamiami Trl Ste 303
Sarasota, FL 34239

Contact Person: Dr. William F. Bennett
(941) 953-5509

Trade Name: ZipE® Knotless Tissue Repair and Attachment Devices

Common Name: Soft Tissue Fixation Device

Classification Name:

- MBI (888.3040) Fastener, fixation, nondegradable, soft tissue
- MAI (888.3030) Fastener, fixation, biodegradable, soft tissue
- KGS (878.4930) Retention device, suture

Predicate Devices:

Predicate	510(k) Number	Device	Manufacturer
Primary (metallic anchor)	K974847	Arthrex Parachute Corkscrew Suture Anchor	Arthrex, Inc.
Additional	K071704	Sleeve and Button Soft Tissue Devices	Biomet Sports Medicine
Primary (resorbable anchor)	K071177	Arthrex Biocomposite Suture Anchors	Arthrex, Inc.
Reference (material)	K983843	Arthrex Bio-Button	Arthrex, Inc.
Reference (material)	K151200	STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device	Ethicon, Inc.

Device Description:

The **ZipE® Knotless Tissue Repair and Attachment Devices** are implantable soft tissue fixation and suture retention devices comprising of a resorbable pledget/button disc ("suture capture" or "capture"), a titanium screw or biocomposite bone anchor ("plug"), an ultra-high molecular weight polyethylene (UHMWPE) braided #2 suture having pre-tied half hitched protuberances along its length, a nitinol wire capture holder and a nitinol wire suture shuttle. All components are preloaded onto a stainless steel insertion driver having a TPE tip protector and a silicone O-ring encircling the diameter of the handle to hold the system in place. The implantable elements of the system are the bone anchor, suture and capture; the other components are part of the driver insertion system.

The capture is designed to interact with the knotted suture by locking with the protuberances on the suture so that once advanced across the protuberance, it cannot move backward. Once the anchor is inserted into the bone, the

pushed down with the stainless steel driver, traveling forward over the knotted suture, preventing movement in the reverse direction, and thereby locking the repair tissue to the underlying tissue.

The **ZipE® Knotless Tissue Repair and Attachment Devices** come with all components pre-assembled into the insertion driver and ready to be operated by the user. Products may be sold separately.

Indications for Use:

The **ZIPE® Knotless Tissue Repair and Attachment Devices** are intended for fixation of tissue to bone and tissue to tissue.

This product is intended for the following indications:

- *Shoulder:* Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
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- *Knee:* Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair
- *Hand/Wrist:* Scapholunate Ligament Reconstruction, Ulnar and Radial Collateral Ligament Reconstruction
- *Elbow:* Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

Non-clinical Testing:

ZIPTEK LLC performed extensive non-clinical testing for the **ZIPE® Knotless Tissue Repair and Attachment Devices**, including:

Bench testing	Static pullout testing Cyclic pullout testing Degradation testing Insert Torque testing
Biocompatibility testing	Systemic toxicity Reverse mutation Intracutaneous injection Kligman maximization Micronucleus assay Lymphoma mutagenesis Intramuscular implantation Pyrogen test Systemic injection test MEM elution test Neutral red uptake test

Sterilization validation	Bioburden EO residual testing Endotoxin (LAL) Validation (*Endotoxin testing is conducted on every batch of the device as part of the release test)
Package and transportation testing	Transportation validation Packaging testing Accelerated aging

Clinical Testing:

None provided as a basis for substantial equivalence.

Technological Characteristics:

The **ZipE® Knotless Tissue Repair and Attachment Devices** and the primary predicate Arthrex Parachute Corkscrew [K974847] are similar in design, have the same intended use and similar indications, technological characteristics and principles of operation. The technological difference between them relies on the locking mechanism of the suture by the suture capture (button disc). The Sleeve and Button Anchor [K071704] also uses a button disc as a suture retention device as part of the anchoring system. The device anchor plug and the primary predicate Arthrex Biocomposite Anchors [K071177] are made of the same material and have the same intended use, similar indications, technological characteristics and principles of operation. The most significant technological difference relies on the eyelet design and suture attachment mechanisms. Some predicate devices have an eyelet and some do not; therefore, this does not represent a new design feature compared to other previously cleared suture anchors. The suture-capture material is made of a PLA/caprolactone. This caprolactone is utilized as a copolymer with other suture materials, an example, the STRATAFIX Knotless Tissue Control Device [K151200]. The Arthrex Bio-Button [K983843] and the Arthrex Parachute Corkscrew [K974847] have a surgical button/capture made from the PLA family of materials.

Substantial Equivalence Summary:

The **ZipE® Knotless Tissue Repair and Attachment Devices** is substantially equivalent to predicate devices, which have the same intended use and similar technological characteristics. Minor differences between **ZipE® Knotless Tissue Repair and Attachment Devices** and the predicate devices do not raise different questions concerning safety and effectiveness and do not adversely impact the performance, function, or intended use of the device, as confirmed by performance testing. Thus, the **ZipE® Knotless Tissue Repair and Attachment Devices** are substantially equivalent to the predicates.