July 25, 2018

S.B.M. SAS Sciences for Bio Materials
Anne Cospin-Latapie
Quality/Regulatory Affairs Manager
ZI du Monge
Lourdes, France 65100

Re: K180960
Trade/Device Name: FIXIT®/ComposiTCP™ Threaded Anchor System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: June 20, 2018
Received: June 25, 2018

Dear Ms. Cospin-Latapie:

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.

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

INDICATIONS FOR USE

510(k) Number (if known): K180960

Device Name: FIXIT® / ComposiTCP™ Threaded Anchor System

Indications for Use:

The FIXIT®/ ComposiTCP™ threaded anchor system is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, but not limited to, the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair; SLAP Lesion Repair; Biceps Tenodesis; Acromio-clavicular Separation Repair; Deltoid Repair; Capsule Shift or Capsulolabral Reconstruction;

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

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

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

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

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

1. SUBMITTER

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Date prepared: June 14, 2018

2. DEVICE

Name of Device	FIXIT®/ ComposiTCP™ Threaded Anchor System
Common or Usual Name	Suture Anchor
Classification Name	Fastener, fixation, biodegradable, soft tissue
Regulatory Class	II
Product Code	MAI

3. PREDICATE DEVICE

FIXIT Threaded Anchor System (K170868)

Referenced devices:

K070673 Force Fiber® Black Co-braid Polyethylene non-absorbable Suture

K063778 Force Fiber® Polyethylene non-absorbable Suture

K160854 Blue BroadBand® Single Flat Suture

K160854 White/Green BroadBand® Single Flat Suture

4. DEVICE DESCRIPTION

FIXIT® / ComposiTCP™ Threaded Anchor System is composed of a bioabsorbable composite anchor (30% β-TCP/ 70%PLDL) pre-loaded on a disposable screwdriver and 2 sutures. Different variations of the product are available depending on the type of suture combination (2 flat sutures, or 1 round + 1 flat)

For each configuration, the implant is supplied sterile, ready to use.

5. INDICATIONS FOR USE

The FIXIT®/ ComposiTCP™ threaded anchor system is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, but not limited to, the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair; SLAP Lesion Repair; Biceps Tenodesis; Acromio-clavicular Separation Repair; Deltoid Repair; Capsule Shift or Capsulolabral Reconstruction;

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

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

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

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

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

FIXIT®/ ComposiTCP™ Threaded Anchor System is compared to FIXIT Threaded Anchor System (K170868) manufactured by S.B.M SAS Science and Bio Materials.

The applicant device has the same intended use as the predicate device.

The technological characteristics of this product are believed to be substantially equivalent as those for the predicate device. This device and its predicates use similar performance characteristics, manufacturing materials, and design.

	FIXIT®/ ComposiTCP™ Threaded Anchor System **Present submission**	**FIXIT® Threaded Anchor System** **K170868 (Predicate device)**
21CFR	888.3030 Single/multiple component metallic bone fixation appliances and accessories	
Product's code	MAI	
Device	Threaded suture anchors	
Indications for use	All these devices include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow,	

statement	and knee. Specific indications are as follows: <u>Shoulder:</u> Bankart Repair; SLAP Repair; Acromio-clavicular Separation; Rotator Cuff Repair; Capsule Repair or Capsulolabral Reconstruction; Biceps Tenodesis; and Deltoid Repair <u>Wrist/Hand:</u> Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction <u>Ankle/Foot:</u> Lateral Stabilization; Medial Stabilization; Achilles Tendon Repair/Reconstruction; Hallux Valgus Reconstruction; and Mid and Forefoot Reconstruction <u>Elbow:</u> Ulnar or Radial Collateral Ligament Reconstruction; Biceps Tendon Reconstruction; and Lateral Epicondylitis Repair <u>Knee:</u> Extra-capsular Repair; Medial Collateral Ligament Repair; Lateral Collateral Ligament Repair; Posterior Oblique Ligament Repair; Joint Capsule Closure; Iliotibial Band Tenodesis; Patellar Realignment and Repair; Patellar Ligament/Tendon Repair; and Vastus Medialis Obliquus (VMO) Muscle Advancement	
Anchor	β-TCP (30%) / Poly Lactid Copolymer (70%)	β-TCP (30%) / Poly Lactid Copolymer (70%)
Resorbable	YES	YES
Suture	Pre-loaded on a disposable screwdriver with 2 round sutures	Pre-loaded on a disposable screwdriver with 2 flat sutures, or 1 round + 1 flat
Model size	Ø 4.5mm x14.5 mm Ø 5.5mm x17.6 mm Ø 6.5mm x17.6 mm	Ø 4.5mm x14.5 mm Ø 5.5mm x17.6 mm Ø 6.5mm x17.6 mm
<u>Mechanical Properties</u> - **Pull-out strength at 12 weeks (≥ 150 N)**	229 ± 19 N (Cf. RD 1124 Report)	220 ± 12 N (Cf. RD 1204 Report)
Sterilization method	Gamma rays 25 kGy minimum	Gamma rays 25 kGy minimum
Labeling	All these devices share same intended use, contra-indications, warnings precautions and potential adverse events	

4. PERFORMANCE DATA

Non-clinical performance testing

Non-clinical testing including chemical, biological and mechanical performances was performed to determine substantial equivalence. The results indicated that the devices were functional within their intended use and equivalent to the predicate devices.

Bacterial endotoxin testing has been completed and results have demonstrated that the proposed devices meet the endotoxin limits.

Clinical performance testing:

Clinical performance data was not included.

5. CONCLUSIONS

The FIXIT®/ ComposiTCP™ Threaded Anchor System is substantially equivalent to its predicate device FIXIT® Threaded Anchor System (K170868). Verification and validation tests demonstrate that the FIXIT® Threaded Anchor System is as safe, as effective, and performs as safely and effectively as its predicate device.