July 26, 2023

Science & Bio materials (S.B.M.) SAS
Anne Cospin
Quality and Regulatory Affairs Director
Zi Du Monge
Lourdes, 65100
France

Re: K231787
Trade/Device Name: ecoFIX®
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, 2023
Received: June 20, 2023

Dear Ms. Cospin:

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,

Jesse Muir -S

Jesse Muir, 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.

Submission Number *(if known)*

K231787

Device Name

ecoFIX®

Indications for Use *(Describe)*

The ecoFIX® threaded anchor system is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, 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.

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) #: K231787

510(k) Summary

Prepared on: 2023-07-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SCIENCE & BIO MATERIALS (S.B.M.) SAS
Applicant Address	ZI DU MONGE LOURDES 65100 France
Applicant Contact Telephone	33562422101
Applicant Contact	Mrs. Anne COSPIN
Applicant Contact Email	anne.cospin@sbm-fr.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ecoFIX®
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Fastener, Fixation, Biodegradable, Soft Tissue
Regulation Number	888.3030
Product Code	MAI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180960	FIXIT® / ComposiTCP™ Threaded Anchor System	MAI
K170868	FIXIT® / ComposiTCP™ Threaded Anchor System	MAI

Device Description Summary

21 CFR 807.92(a)(4)

1. DEVICE DESCRIPTION
ecoFIX® is an extension the FIXIT® / ComposiTCP™ threaded anchor system previously cleared by the FDA (K170868 & K180960).
ecoFIX® is a threaded anchor system which comprises an anchor made of DUOSORB® 30, a composite bioabsorbable material composed of 30 % Beta-tricalcium phosphate (β-TCP) and 70 % Poly L,DL-lactic acid (PLDLLA), and sutures made of ultra-high molecular weight polyethylene (UHMWPE). Different variants of the product are available depending on the number and type of suture combination (2 round sutures, 2 round needled sutures, 3 round sutures, 2 flat sutures, or knotless anchor).
The implant is supplied sterile, ready to use.
The implant is available in the following configurations, supplied with a reusable screwdriver:
• ecoFIX®: hexagonal footprint anchor (3 sizes Ø4.5, Ø5.5, Ø6.5) suppplied in an implant holder with 2 round sutures ;
• ecoFIX® Needle: hexagonal footprint anchor (3 sizes Ø4.5, Ø5.5, Ø6.5) supplied in an implant holder with 2 round needled sutures ;
• ecoFIX® +: hexagonal footprint anchor (1 size Ø5.5) supplied in implant holder with 3 round sutures ;
• ecoFIX® Band: hexagonal footprint anchor (3 sizes Ø4.5, Ø5.5, Ø6.5) supplied in an implant holder with 2 flat sutures ;
• ecoFIX® Knotless: hexagonal footprint anchor (3 sizes Ø4.5, Ø5.5, Ø6.5) supplied in an implant holder.

2. MATERIALS
Implant(s) :
- Anchor: DUOSORB®30 (30% β-TCP / 70% PLDLLA)
- Sutures:
o Blue and white sutures: Ultra-high molecular weight polyethylene (UHMWPE)

o White/black suture: UHMWPE + black polyamide (nylon) monofilament
o Needle : stainless steel and medical grade silicone coating

Implant holder:
- Polyamide

Reusable screwdriver:
- Screwdriver handle: Silicone / Polycarbonate
- Screwdriver shaft: Stainless steel (304L)

3. INDICATIONS FOR USE
The ecoFIX® threaded anchor system is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, 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.

4. PERFORMANCE DATA
Non-clinical performance testing:
Non-clinical testing including biocompatibility, 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. SUBSTANTIAL EQUIVALENCE
The modifications to FIXIT® Threaded Anchor System (K170868 & K180960) consist of additional variants eco-designed with the aim of limiting waste in the operating room by using a reusable rather than a single-use screwdriver.
The additional ecoFIX® Threaded Anchor System is substantially equivalent to its predicate device FIXIT® Threaded Anchor System (K170868 & K180960) in terms of intended use, material, design, mechanical properties and function.
Minor differences between the ecoFIX® threaded anchor system and the predicate device do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ecoFIX® threaded anchor system is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the submitted device are the same as the ones of the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The modifications to FIXIT® Threaded Anchor System (K170868 & K180960) consist of additional variants eco-designed with the aim of limiting waste in the operating room by using a reusable rather than a single-use screwdriver.
The additional ecoFIX® Threaded Anchor System is substantially equivalent to its predicate device FIXIT® Threaded Anchor System (K170868 & K180960) in terms of intended use, material, design, mechanical properties and function.
Minor differences between the ecoFIX® threaded anchor system and the predicate device do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Performance tests were carried out to evaluate the ease of use, driver hold, needle hold and the insertion, pullout/slippage performances of the ecoFIX® range of devices. The results demonstrated that the subject device is substantially equivalent to its predicate device.