March 8, 2023

BAAT Medical Products B.V.
Jasper Springer, Ph.D.
Regulatory Affairs Officer
F. Hazemeijerstraat 800-Building A04
Hengelo, Overijssel 7555 RJ
Netherlands

Re: K220966
Trade/Device Name: SINEFIX
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 8, 2023
Received: February 8, 2023

Dear Dr. Springer:

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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
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)*
K220966

Device Name
SINEFIX

Indications for Use *(Describe)*
The PEEK SINEFIX is intended for soft tissue to bone reattachment in rotator cuff repairs for tendon ruptures up to 2 cm.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Summary

1. Applicant/Submitter

Submitter Name:	BAAT Medical Products B.V.
Submitter Address:	F. Hazemeijerstraat 800 - Building A04 7555 RJ Hengelo The Netherlands
Phone Number:	+31-(0)88-5656600
Contact person:	Jasper Springer

Date Prepared:	March 30, 2022

2. Device

510(k) Number	K220966
Device Trade name:	SINEFIX
Common Name:	Not Applicable
Classification:	Smooth or threaded metallic bone fixation fastener (21 CFR Sec. 888.3040)
Class:	II
Product Code:	MBI - Fastener, Fixation, Nondegradable, Soft Tissue
Review Panel:	Office of Health Technology 6: Orthopedic Devices

3. Predicate Device

Primary Predicate: Coronet Soft Tissue Fixation System (K200028)

Reference devices: Arthrex Tenodesis Screw Family (K051726)
Acufex Spiked Washer System (K994202)
Interference Screw (K062466)
ZipE Knotless Tissue Repair and Attachment Devices (K162429)
Bio-Button (K983843)
FOOTPRINT Ultra PK Suture Anchor (K123579)
SwiveLock Anchors (K101823)
ExoShape Duo Soft Tissue Fastener (K132783)
PITON Fixation Implant System (K091870)

4. Description of the Device

The SINEFIX is a PEEK implant which can be used to re-attach a ruptured rotator cuff tendon to the humerus of the shoulder. The implant can be used to re-attach complete or partially ruptured tendons up to 2 cm to facilitate the healing of the natural bone-tendon interface. The implant consists of a baseplate with a lateral and a medial anchor. The baseplate is placed over the tendon and attached to the humerus with the anchors. The medial anchor goes through the tendon, while the lateral anchor goes directly into the bone, lateral of the tendon.

5. Intended Use/Indication for Use Statement

The PEEK SINEFIX is intended for soft tissue to bone reattachment in rotator cuff repairs for tendon ruptures up to 2 cm.

6. Summary of Technological Characteristics of the Device Compared to Predicate devices

A comparison of technological characteristics is made between the SINEFIX and the predicate devices in Table 5.1.

Table 5.1: Technical Comparison, Subject Device and Predicate.

	Subject Device	*Primary Predicate*
510(k)	K220966	K200028
Device name	SINEFIX	Coronet Soft Tissue Fixation System
Manufacturer	BAAT Medical Products BV	CoNextions Medical, Inc.
Product code	MBI	MBI
Regulation #	888.3040	888.3040
Class	II	II
Image		
Indications for Use	The PEEK SINEFIX is intended for soft tissue to bone reattachment in rotator cuff repairs for tendon ruptures up to 2 cm.	… intended for fixation of tissue to bone and tissue to tissue. This product is intended for the following indications: Shoulder: Rotator Cuff Repair...
Material	PEEK	PEEK, Stainless Steel
Size	Baseplate: 10mm x 8mm (17.7mm) - Plate thickness 0.7mm Medial Anchor: Ø3mm (4.42mm) x	Button: Ø 8.7mm x 2.4mm - Plate thickness 0.5mm

	16.24mm Lateral Anchor: Ø4.02 (6.8mm) X 18.21mm	#2 suture (FiberWire® Suture, Arthrex): 0.5mm Anchor: Ø 3.5mm x 12.3mm

7. Summary of Performance Data and Design Controls

The SINEFIX has the same technological characteristics as the predicate devices including design, intended use and material composition.

The SINEFIX has been subject to non-clinical testing, including:

- Insertion testing
- ASTM F543-17 Pullout testing
- ASTM F543-17 Pullout testing after cyclic loading
- Static tensile test
- Dynamic testing pullout strength after cyclic loading
- Pyrogenicity and endotoxins

In accordance with the guidance for Industry and FDA Staff: Bone Anchors - Premarket Notification (510(k)) Submissions, March 3, 2020.

- Packaging testing was performed in accordance with ISO 11607-1/2 and has proven a shelf life of 5 years;
- Biological evaluation was performed in accordance with ISO 10993-1 and the Guidance for Industry and FDA Staff - Use of International Standard ISO 10993, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", September 4, 2020;
- Sterilization validation was performed in accordance with ISO 11137-1/2 and has proven a SAL 10^{-6};
- Reprocessing validation was performed for the cleaning, disinfection, steam sterilization and drying of the reusable surgical instruments in accordance with the Guidance for Industry and FDA Staff - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, March 17, 2015;

Results of the performed tests demonstrate that the SINEFIX are substantially equivalent to legally marketed predicate devices.

8. Conclusion of Substantial Equivalence

The purpose of the traditional 510(k) is to receive regulatory clearance to introduce the SINEFIX to interstate commerce. Substantially equivalence has been demonstrated to the cited predicate device.