March 16, 2026

BAAT Medical Products B.V.
Jasper Springer
Regulatory Affairs Officer
F. Hazemeijerstraat 800
Bldg. A04
Hengelo, 7555RJ
Netherlands

Re: K254176
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 16, 2026
Received: February 17, 2026

Dear Jasper 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254176

Please provide the device trade name(s).

SINEFIX

Please provide your Indications for Use below.

The SINEFIX is intended for fixation of soft tissue to bone. The SINEFIX is intended for the following indications:
o Shoulder: Rotator Cuff Repairs, Deltoid Repair.
o Foot/Ankle: Achilles Tendon Repair.
o Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair. Patellar Tendon Repair, Quadriceps Tendon Rupture Repair.
o Elbow: Biceps Tendon Reattachment. Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.
o Hip: Gluteus Medius repair, Gluteus Minimus repair.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: J. Springer

Date Prepared: December 22, 2025

2. Device

Device Trade name: SINEFIX

Common Name: Not applicable

Classification: Smooth or threaded metallic bone fixation fastener (21 CFR Sec. 888.3040)

Product Code: MBI - Fastener, Fixation, Nondegradable, Soft Tissue

Review Panel: Office of Health Technology 6: Orthopedic Devices

3. Predicate Device

SINEFIX (K220966)

4. Description of the Device

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

5. Intended Use/Indication for Use Statement

The SINEFIX is intended for fixation of soft tissue to bone. The SINEFIX is intended for the following indications:

- Shoulder: Rotator Cuff Repairs, Deltoid Repair.
- Foot/Ankle: Achilles Tendon Repair.
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair. Patellar Tendon Repair, Quadriceps Tendon Rupture Repair.
- Elbow: Biceps Tendon Reattachment. Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.
- Hip: Gluteus Medius repair, Gluteus Minimus repair.

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

A comparison of technological characteristics is made between the modified SINEFIX and the predicate devices in Table 1.

Table 1. Technical Comparison, Subject Device and Predicates.

	Subject Device	*Primary Predicate*
510(k)	Not yet assigned	K220966
Device name	SINEFIX	SINEFIX
Manufacturer	BAAT Medical Products B.V.	BAAT Medical Products B.V.
Product code	MBI	MBI
Regulation #	888.3040	888.3040
Class	II	II
Image		
Indications for Use	The SINEFIX is intended for fixation of soft tissue to bone. The SINEFIX is intended for the following indications: ○ Shoulder: Rotator Cuff Repairs, Deltoid Repair. ○ Foot/Ankle: Achilles Tendon Repair. ○ Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair. Patellar Tendon Repair, Quadriceps Tendon Rupture Repair. ○ Elbow: Biceps Tendon Reattachment. Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair. ○ Hip: Gluteus Medius repair, Gluteus Minimus repair.	The PEEK SINEFIX is intended for soft tissue to bone reattachment in rotator cuff repairs for tendon ruptures up to 2 cm.
Material	PEEK	PEEK
Size	Baseplate: 10mm × 8mm (17.7mm) - Plate thickness 0.7mm. Medial Anchor: Ø3mm (4.42mm) × 16.24mm. Lateral Anchor: Ø4.02 (6.8mm) × 18.21mm	Baseplate: 10mm × 8mm (17.7mm) - Plate thickness 0.7mm. Medial Anchor: Ø3mm (4.42mm) × 16.24mm. Lateral Anchor: Ø4.02 (6.8mm) × 18.21mm

7. Summary of Performance Data and Design Controls

The SINEFIX has the same intended use as the predicate device. Verification and validation activities (including mechanical performance evaluation per ASTM F3960-24) demonstrated that the modified device continues to meet its design specifications and performs equivalently to the predicate device. Minor technological differences between the modified SINEFIX and the predicate device do not raise

new questions of safety or effectiveness and do not adversely affect the intended use, fundamental technology, or overall performance of the device as confirmed by verification and validation testing.

8. Conclusion of Substantial Equivalence

The differences encountered do not negatively impact the overall safety and effectiveness of the modified SINEFIX. Therefore, it can be concluded that the modified SINEFIX is a safe and effective device and is substantially equivalent to the identified predicate systems.