March 6, 2026

Theramicro
Christine Scifert
Head of QA/RA
51 Germantown Court
Suite 200
Cordova, Tennessee 38018

Re: K253538
Trade/Device Name: TeKBrace Knotless Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 4, 2026
Received: February 5, 2026

Dear Christine Scifert:

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.	K253538

Please provide the device trade name(s).

TeKBrace Knotless Anchor

Please provide your Indications for Use below.

TheraMicro TeKBrace Knotless Anchors are intended for use in the following applications:
Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.
Foot/Ankle: Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus reconstruction, Midfoot reconstruction, Metatarsal Ligament/Tendon Repair, and Bunionectomy.
Knee: Anterior Cruciate Ligament Repair (4.75- 5.5 Only), Medial collateral and Lateral collateral ligament repair, Patellar tendon repair and Posterior oblique ligament repair, Extra Capsular Reconstruction, Illiotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. Quadriceps Tendon Repair (4.75 Only), Meniscal Root Repair (4.75 Only), Secondary or adjunct fixation for ACL/PCL reconstruction or repair (4.75-5.5 only), MPFL Repair/Reconstruction (3.9 Only)
Hand and Wrist: Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament and Ulnar collateral ligament reconstruction.
Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.
Hip: Capsular Repair, Acetabular labral repair, Gluteus Medius Repair (4.75 - 5.5 mm only), and Proximal Hamstring Repair (4.75 - 5.5 only).

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K253538

510(k) Summary

TeKBrace Knotless Anchor

11 November 2025

Company: TheraMicro
51 Germantown Court, Suite 200
Cordova, TN 38018

Company Contact: Christine Scifert
Head of RA/QA
TheraMicro
Phone: (901) 831-8053
Email: cscifert@theramicro.com

Trade Name: TeKBrace Knotless Anchor

Common Name: fastener, fixation, nondegradable, soft tissue

Classification: Class II

Regulation: 21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)

Panel: Orthopedic

Product Code: MBI

Primary Predicate: Arthrex Swivelok Anchors – K203495

Additional Predicates: In2Bones Hercules Suture Anchor System – K201636
Artelon ATL Anchors – K200503

Device Description:

The TeKBrace Knotless Anchors are part of the TeKBrace System which is intended for the fixation of soft tissue to bone. The TekBrace Knotless Anchor consists of a two-piece anchor manufactured from polyetherether-ketone (PEEK) and is available in three sizes (3.9mm, 4.75mm and 5.5mm). The knotless anchor is a sterile two-component suture anchor comprised of an eyelet and hollow anchor body. The TeKBrace Knotless Anchor will be provided in a kit also containing the TeKBrace Solo Soft Tissue Reinforcement Device previously cleared in K251063. Additionally, anchors and eyelets may be provided packaged separately for convenience. All devices are single-use only and provided sterile via gamma irradiation.

There are two kit configurations including the TekBrace Knotless Anchor and TekBrace Solo Devices. In these configurations the TekBrace Solo acts as the suture when compared to predicate devices with an anchor / suture construct. The anchor may be provided preloaded with TeKBrace Solo on an inserter or

the anchor may be provided not pre-loaded, but in the same packaging as the TeKBrace Solo Device. Both configurations include the instruments required for the procedure.

Indications for Use:

TheraMicro TeKBrace Knotless Anchors are intended for use in the following applications:

Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.

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Hand and Wrist: Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament and Ulnar collateral ligament reconstruction.

Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.

Hip: Capsular Repair, Acetabular labral repair, Gluteus Medius Repair (4.75 - 5.5 mm only), and Proximal Hamstring Repair (4.75 - 5.5 only).

Substantial Equivalence:

The subject components are substantially equivalent to the predicate In2Bones Hercules Suture Anchors cleared under K201636, Arthrex SwiveLok Anchors (primary predicate) cleared under K101823, K203435, K230435 and Artelon ATL Anchors cleared under K200503. The subject components are similar in indications, geometry, and materials to the predicates. Reference predicate for the suture implant is TheraMicro TeKBrace Solo Soft Tissue Reinforcement Device under K251063.

Performance Testing:

Insertion and Removal Torque, Torque Capacity, and Pullout “Pre-” and Post-Fatigue testing were performed for the subject Anchors and the predicate Arthrex and Artelon anchors. Per Draft Guidance for Premarket Notification (510(k)) for Bone Anchors issued on January 3, 2017, mechanical testing was done in accordance with ASTM F543-07 to evaluate the anchors and establish substantial equivalence.

Conclusion:

The subject device is determined to be substantially equivalent to the predicate devices.