June 9, 2026

TheraMicro
Christine Scifert
Head of RA/QA
51 Germantown Ct.
Suite 200
Cordova, Tennessee 38018

Re: K261621
Trade/Device Name: TekBrace Solo Soft Tissue Reinforcement Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: QUW, FTL, OWX
Dated: May 15, 2026
Received: May 15, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Thomas Mcnamara -S

For: 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.	K261621

Please provide the device trade name(s).

TekBrace Solo Soft Tissue Reinforcement Device

Please provide your Indications for Use below.

The TeKBrace Solo Soft Tissue Reinforcement Device is a single use device intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon and ligament repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments.

The TeKBrace Solo Soft Tissue Reinforcement Device is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the 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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

TeKBrace Solo Soft Tissue Reinforcement Device

14 May 2026

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 Solo Soft Tissue Reinforcement Device

Common Name: mesh, surgical, non-resorbable, orthopedics, reinforcement of ligament

Classification: Class II

Regulation: 21 CFR 878.3300 (Surgical mesh)

Panel: General and Plastic Surgery

Product Code: QUW, FTL, OWX

Primary Predicate: TheraMicro TeKBrace Solo Soft Tissue Reinforcement Device – K251063

Device Description:

The TheraMicro TeKBrace Solo Soft Tissue Reinforcement Device is a single use device intended to be used for reinforcement of soft tissue. The product is offered in a central tubular weave tape that tapers down to cords at both ends. The implant is available in multiple size configurations.

This submission introduces additional device configurations that vary in length and width. Many configurations of the device will have pockets which provide access to the inside of the tubular section. The product is substantially equivalent in material and manufacturing compared to the TeKBrace Solo Soft Tissue Reinforcement Device (K251063).The TeKBrace solo configurations included in this submission are similar to the existing TheraMicro TeKBrace Solo device in intended use, material and design, including a central tubular section tapering down to cords at the end.

TeKBrace Solo is manufactured from non-absorbable polyethylene terephthalate (PET), commercially known as polyester. The implant is manufactured from fibers of long-chain,

linear polyester having recurrent aromatic rings. The device also incorporates Cottony II green PET suture for pocket location visibility.

Indications for Use:

The TeKBrace Solo Soft Tissue Reinforcement Device is a single use device intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon and ligament repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments.

The TeKBrace Solo Soft Tissue Reinforcement Device is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the repair.

Substantial Equivalence:

The subject TekBrace Solo Soft Tissue Reinforcement Device is substantially equivalent to the following predicate devices:

Primary Predicate:
TheraMicro TeKBrace Solo Soft Tissue Reinforcement Device – K251063
Additional Predicates:
Xiros Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device – K222978
Xiros Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device – K220091

The subject TekBrace Solo Soft Tissue Reinforcement Device is substantially equivalent to the predicate TeKBrace Solo Soft Tissue Reinforcement Device (K251063) and Xiros Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device (K222978 and K220091) in material and manufacturing. The Primary predicate device is K251063. The subject components are substantially equivalent to the primary predicate in indications, manufacturing, and materials. TeKBrace Solo is similar to the Xiros Infinity-Lock predicate in intended use, material and design, including a central tubular section tapering down to cords at the end.

Performance Testing:

The following performance testing has been completed on the subject devices: Tensile testing to determine ultimate tensile strength (pre fatigue) &Tensile testing to determine fixation strength when the device is fixed with 2 interference screws

Conclusion:

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