August 15, 2025

Dunamis Medical, LLC
℅ Sarah Pleaugh
Director, Regulatory Affairs
MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, District of Columbia 20001

Re: K250867
Trade/Device Name: Dunamis Screw and Suture Locking System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, MBI, GAT
Dated: July 24, 2025
Received: July 24, 2025

Dear Sarah Pleaugh:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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, MS
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250867

Device Name
Dunamis Screw and Suture Locking System

Indications for Use *(Describe)*
The Dunamis Screws are intended to be used as stand-alone bone screws indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bone appropriate for the size of the device.

When used in conjunction with Dunamis Force DFX Suture or Suture Tape, the Dunamis Screw and Suture Locking System is intended to be used for fixation of bone-to-bone or soft tissue-to-bone. The components are intended to serve as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Specifically, Dunamis will be offering these devices for use in orthopedic procedures, such as ACL/PCL repair and reconstruction for the adult and pediatric patient population when the device does not bridge, disrupt, or interfere with the growth plate; MCL, POL, LCL repair and reconstruction; IBT and PRT repair; and MPFL, ALL, Quadriceps Tendon, PLC repair and reconstruction. When used in conjunction with the Dunamis Screws, the Suture Locking System can be used as a cerclage to treat bone fractures, such as patella, greater tuberosity, or olecranon fractures.

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.

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K250867

Device Trade Name: Dunamis Screw and Suture Locking System

Manufacturer:
Dunamis Medical, LLC
104 Camellia Ave Ste B
Greenville, AL 36037

Contact:
Sarah Pleaugh
Director, Regulatory Affairs
MCRA, LLC

Prepared by:
MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: August 7, 2025

Classification:

Class	II
Medical Specialty	Orthopedics/Plastic Surgery
Regulation	888.3040; Smooth or threaded metallic bone fixation fastener 878.5000: Nonabsorbable Poly(ethylene) Terephthalate Surgical Suture
Product Codes	HWC, MBI, GAT
Common Name	Screw, Fixation, Suture Fastener, fixation, nondegradable, soft tissue

Predicates:

Predicate	Manufacturer	Device Name	K Number
Primary	Arthrex	Blunt Tip Screws with FiberTape	K143702
Additional	Dunamis	Fixation Button System	K191319
Additional	Arthrex	TightRope II	K241235
Reference	Paragon 28, Inc.	Monster Screw System	K203011
Reference	Dunamis	Force DFX Suture	K150327
Reference	Dunamis	Force DFX Tensile Tape Suture	K153746

Indications For Use:
The Dunamis Screws are intended to be used as stand-alone bone screws indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bone appropriate for the size of the device.

When used in conjunction with Dunamis Force DFX Suture or Suture Tape, the Dunamis Screw and Suture Locking System is intended to be used for fixation of bone-to-bone or soft tissue-to-bone. The components are intended to serve as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Specifically, Dunamis will be offering these devices for use in orthopedic procedures, such as ACL/PCL repair and reconstruction for the adult and pediatric patient population when the device does not bridge, disrupt, or interfere with the growth plate; MCL, POL, LCL repair and reconstruction; IBT and PRT repair; and MPFL, ALL, Quadriceps Tendon, PLC repair and reconstruction. When used in conjunction with the Dunamis Screws, the Suture Locking System can be used as a cerclage to treat bone fractures, such as patella, greater tuberosity, or olecranon fractures.

Device Description:
The Dunamis Screw and Suture Locking System is to be used for fixation of bone-to-bone or soft tissue-to-bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. The devices are intended to be used in the adult or pediatric patient population, when the device does not bridge, disrupt, or interfere with the growth plate.

The Dunamis Screw and Suture Locking System consists of standalone bone screws, and various components which are compatible with previously cleared Dunamis Fixation Button System, Force DFX sutures and suture tapes, including: screws with suture locking features and suture wheel with various adapter options. The standalone screws are provided in various diameters, lengths, and configurations including headed and headless styles with various overall and threaded lengths. Screws with suture locking features are available in various diameters, lengths, and configurations. The suture wheel is available for standalone use with sutures or for use with compatible orthopedic plates with two adapter options (threaded or non-threaded post). The new components are manufactured from stainless steel and titanium alloy.

Predicate Device:
Dunamis submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the Dunamis Screw and Suture Locking System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be

Predicate	Manufacturer	Device Name	K Number
Primary	Arthrex	Blunt Tip Screws with FiberTape	K143702
Additional	Dunamis	Fixation Button System	K191319
Additional	Arthrex	TightRope II	K241235
Reference	Paragon 28, Inc.	Monster Screw System	K203011
Reference	Dunamis	Force DFX Suture	K150327
Reference	Dunamis	Force DFX Tensile Tape Suture	K153746

Performance Testing Summary:
Non-clinical performance data included ASTM F543 screw testing, static and dynamic construct testing, and engineering worst-case rationales. The non-clinical performance data demonstrate that the Dunamis Screw and Suture Locking System is substantially equivalent to the predicate devices.

Substantial Equivalence Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods.

While the subject Dunamis Screw and Suture Locking System has similar technological characteristics as the predicate and reference devices, they are not identical. The subject Suture Locking Screws with Button Cap Suture Locking Features utilizes the internal geometry and knotless suture locking technology as the Dunamis Button Fixation System (K191319). The subject Suture Locking Screws with Locking Pin is a variation of the Dunamis Fixation Button (K191319) and works in the same way when mated with the screw in its ability to lock sutures into place. Both the subject Suture Locking Screws and the predicate Dunamis Button Fixation System (K191319) are compatible with the Dunamis Force DFX Suture (K150327) and Dunamis Force DFX Tensile Tape Suture (K153746).

Overall, the subject Dunamis Suture Locking Screws with locking features (i.e., button cap or locking pin) are similar to the primary predicate, Arthrex Blunt Tip Screws with Fiber Tape (K143702), both consisting of screws used with a compatible suture. The primary difference between the subject and predicate constructs is that the sutures are locked with knots for the predicate device (K143702) rather than a button cap or locking pin. The subject locking technology however, is based on the fundamental suture locking technology in the previously cleared Dunamis Fixation Button System (K191319), while also serves as the basis for the subject Suture Wheel. The subject Suture Wheel is to be used in a standalone configuration or with compatible orthopedic plates cleared for the same intended uses. Dynamic and static construct testing was performed to confirm the subject Dunamis Suture Locking Screws and Suture Wheel exhibits sufficient static and dynamic strength.

The subject Standalone Screws are similar to the reference device, Paragon 28 Monster Screw System (K203011), provided in the same sizes (diameter and lengths), manufactured of the same materials and have the same application. Mechanical testing of the subject and predicate screws demonstrated substantially equivalent performance.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above. The Dunamis Screw and Suture Locking System is as safe, as effective, and performs as well as, or better, than the predicate devices.