August 29, 2019

Dunamis LLC
% Hollace Saas Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K191319
Trade/Device Name: Dunamis Fixation Button System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HTN
Dated: July 24, 2019
Received: July 24, 2019

Dear Ms. Rhodes:

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,

Laurence D. Coyne, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191319

Device Name
Dunamis Fixation Button System

Indications for Use *(Describe)*
The Dunamis Fixation Button System is 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, the Dunamis Fixation Button System is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon repair/ reconstruction, including providing fixation during the healing process following acromioclavicular separations, as an adjunct to fracture repair in syndesmotic trauma, and ACL and PCL repair.

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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510(k) Summary

Manufacturer: Dunamis Medical , LLC
509 E. Commerce Street, Suite 3
Greenville, AL 36037
Phone: 731.217.2533

Contact: Dr. PrithviRaj Chavan
President

Prepared By: MCRA, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: August 28, 2019

Device Trade Name: Dunamis Fixation Button System

Device Common Name: Fastener, fixation, nondegradable, soft tissue

Classification: 21 CFR 888.3040 – Fastener, fixation, nondegradable, soft tissue
21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories

Class II

Product Codes: MBI, HTN

Indications for Use:
The Dunamis Fixation Button System is 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, the Dunamis Fixation Button System is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon repair/ reconstruction, including providing fixation during the healing process following acromioclavicular separations, as an adjunct to fracture repair in syndesmotic trauma, and ACL and PCL repair.

Device Description:
The Dunamis Fixation Button 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 Dunamis Fixation Button System consists of titanium fixation buttons, non-absorbable suture loops, optional passing sutures, and optional button supports.

Predicate Devices:
The Dunamis Fixation Button System is substantially equivalent to the following predicates with respect to indications, design, material and function: Arthrex TightRope (K043248, K052776, K112990), RiverPoint OrthoButton CL (K160655), RiverPoint OrthoButton AL (K171060) and Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device (K082095). The sutures proposed for use with the subject system are the same as those used with the reference device, Dunamis Force DFX Suture (K150327), with respect to material, design, and function.

Substantial Equivalence:
Non-clinical testing performed included static testing, dynamic testing, sterilization, sterile barrier packaging performance and aging of sterile medical device. The non-clinical performance testing conducted demonstrates that the insertion and fixation properties of the Dunamis Fixation Button System (with Continuous Loop or Adjustable Loop) are substantially equivalent to the predicate device, Arthrex TightRope (K112990). Additionally, the Dunamis Fixation Button System is in compliance with LAL testing requirements for orthopedic implants per AAMI ST-72 testing.