February 14, 2020

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

Re: K193245
Trade/Device Name: Dunamis PunchTac Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 17, 2020
Received: January 17, 2020

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,

Laura C. Rose, PhD
Acting 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)*
K193245

Device Name
Dunamis PunchTac Suture Anchors

Indications for Use *(Describe)*
The Dunamis PunchTac Suture Anchors are intended to be used for reattachment of soft tissue to bone for the following indications:

Shoulder
Capsular stabilization
Bankart repair
Anterior shoulder instability repair
SLAP lesion repairs
Capsular shift or capsulolabral reconstructions
Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Elbow
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Biceps tendon reattachment

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/ reconstructions
Achilles tendon repairs/ reconstructions
Midfoot reconstructions
Metatarsal ligament/ tendon repairs/ reconstructions
Bunionectomy

Knee
Extra-capsular repairs: medial collateral ligament, lateral collateral ligament, posterior oblique ligament
Patellar realignment and tendon repairs: vastus medialis obliquous advancement, Iliotibial band tenodesis

Hip
Hip capsule repair
Acetabular labrum reattachment
Abductor tendon repair (in anchors 4.5mm – 6.5mm)

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.

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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: January 17, 2020

Device Trade Name: Dunamis PunchTac Suture Anchors

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

Classification: 21 CFR 888.3040 – Fastener, fixation, nondegradable, soft tissue

Class II

Product Codes: MBI

Indications for Use:
The Dunamis PunchTac Suture Anchors are intended to be used for reattachment of soft tissue to bone for the following indications:

Shoulder
Capsular stabilization
Bankart repair
Anterior shoulder instability repair
SLAP lesion repairs
Capsular shift or capsulolabral reconstructions
Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Elbow
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair

Biceps tendon reattachment

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/ reconstructions
Achilles tendon repairs/ reconstructions
Midfoot reconstructions
Metatarsal ligament/ tendon repairs/ reconstructions
Bunionectomy

Knee
Extra-capsular repairs: medial collateral ligament, lateral collateral ligament, posterior oblique ligament
Patellar realignment and tendon repairs: vastus medialis obliquous advancement, Iliotibial band tenodesis

Hip
Hip capsule repair
Acetabular labrum reattachment
Abductor tendon repair (in anchors 4.5mm – 6.5mm)

Device Description:
The Dunamis PunchTac Suture Anchors is a sterile single use implantable suture anchor system designed to provide fixation and reattachment of soft tissue to bone. The system consists of the following components:

- Suture Anchor (threaded, push-in and knotless designs)
- USP Size 2, White & Blue, CoBraid Ultra High Molecular Weight Polyethylene Suture(s) or Suture Tape (provided in configurations with suture only)
- Inserter Tool

Predicate Devices:
The Dunamis PunchTac Suture Anchors with knotless anchors is substantially equivalent to the Dunamis Suture Anchor PEEK (K160996) with respect to indications, design, materials, and function. The Dunamis PunchTac Suture Anchors is substantially equivalent to the reference predicates, Smith & Nephew OSTEORAPTOR (K082215) and Smith & Nephew TWINFIX (K112526) with respect to indications and mechanical performance. The information summarized in the Design Control Activities Summary demonstrates that the modified Dunamis PunchTac Suture Anchors met the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:
The subject device underwent pull-out strength and insertion testing. The results of this testing demonstrates that the subject components met the pre-determined acceptance criteria identified in the Design Control Activities. Additionally, the Dunamis PunchTac Suture Anchors is in compliance with LAL testing requirements for orthopaedic implants.