DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 6, 2016

Dunamis LLC
% Mr. Robert Dean
Senior Consultant
LexaMed
705 Front Street
Toledo, Ohio 43605

Re: K160996
Trade/Device Name: Dunamis Suture Anchor PEEK 3.0mm, 3.5mm, 4.5mm, 5.5mm, 6.5mm
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 31, 2016
Received: April 8, 2016

Dear Robert Dean:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160996

Device Name

Dunamis Suture Anchor PEEK 3.0mm, 3.5mm, 4.5mm, 5.5mm, 6.5mm

Indications for Use *(Describe)*

The Dunamis Suture Anchor suture anchors are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder
Capsular Stabilization
- Bankart Repair
- Anterior Shoulder Instability
- SLAP lesion repairs
- Capsular Shift or capsulolabral reconstructions

Acromioclavicular separation repairs
Deltoid Repairs
Rotator Cuff tear repairs
Biceps tenodesis

Elbow, Wrist, and Hand
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Biceps tendon reattachment

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

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Dunamis Suture Anchor PEEK 3.0mm, 3.5mm, 4.5mm, 5.5mm, 6.5mm

Date Prepared: June 1, 2016

A. Submitters Name:

Dr. Prithvi Raj Chavan
Dunamis, LLC.
693 Sherling Lake Rd., Apt 122
Greenville, AL. 36037
(p) 731-217-2533
Email: dr.raj76@gmail.com

B. Company Contact

Dr. Prithvi Raj Chavan
Dunamis, LLC.
693 Sherling Lake Rd., Apt 122
Greenville, AL. 36037

C. Device Name

Trade Name: Dunamis Suture Anchor PEEK 3.0mm, 3.5mm, 4.5mm, 5.5mm, 6.5mm
Common Name: Suture Anchor
Classification Name: fastener, fixation, non-degradable, soft tissue
Product Code: MBI
Regulation Number: 21CFR888.3040

D. Predicate Devices: The Dunamis Suture Anchor is substantially equivalent in Intended use and performance to the following legally marketed devices in commercial distribution: Smith & Nephew Osteoraptor 2.3 Suture Anchor K082215, Smith & Nephew Twinfix PK FT Suture Anchor K072785 .

E. Description of Device

The Dunamis Suture Anchor 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
- Teleflex Force Fiber Suture(s), USP Size 2, White & Blue, CoBraid Ultra High Molecular Weight Polyethylene
- Inserter tool

The Dunamis Suture Anchor is packaged ready to use condition and provides aseptic O.R delivery. The system is provided complete and is not intended to be used or integrated with other bone anchor fixation implantable devices.

F. Intended Use

Indications

The Dunamis 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

G. Comparison of Technological Characteristics

The Dunamis Suture Anchor is substantially equivalent to the predicate device. The proposed and predicate devices are similar in design, operate on the same principles, have the same indications and intended use and exhibit similar fixation properties.

H. Summary Performance Data

The non-clinical performance testing conducted demonstrates that the insertion and fixation properties of the Dunamis Suture Anchor are substantially equivalent to the predicate devices.

Overall Performance Testing includes:

- Axial Pull-Out Strength
- Biocompatibility
- Sterilization Validation
- Ethylene Oxide Residuals
- Sterile Barrier Packaging performance
- Aging of Sterile Medical Device