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

March 3, 2016

Dunamis LLC
Mr. Robert O. Dean
Compliance Systems International, LLC
1083 Delaware Avenue
Buffalo, NY 14209

Re: K153746
Trade/Device Name: Dunamis Force DFX Tensile Tape
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: December 21, 2015
Received: December 29, 2015

Dear Mr. 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 Part 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153746

Device Name
Dunamis Force DFX Tensile Tape Sutures

Indications for Use *(Describe)*
The Dunamis Force DFX Tensile Tape Sutures are indicated for use in approximation and/or ligation of soft tissues including use of allograft tissue for orthopaedic surgeries".

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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510K Summary

Rev.1

1. **Submitter:** Dr. Prithvi Raj Chavan
Dunamis, LLc.
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Apt. 122
Greenville, AL. 36037
(p) 731-217-2533
Email: dr.raj76@gmail.com

2. **Date Prepared**: 03/02/16

3. **Name of Device:**
   - Proprietary Trade Name: Dunamis Force DFX Tensile Tape Suture
   - Common Name: Suture, Polyethylene Synthetic Non-Absorbable Surgical Suture
   - Classification Name: Non-absorbable poly (ethylene terephthalate) surgical suture
   - Code: GAT
   - Regulation:878.5000

4. **Identification of the legally marketed device (predicate):**
   Teleflex Force Fiber OrthoTape Polyethylene Non-Absorbable Surgical Sutures, K150438.

5. **Description of the device**: The Dunamis Force DFX Tensile Tape Sutures are sterile single use sutures used in approximation and/or ligation of soft tissues, including use in allograft tissue for orthopaedic surgeries. Force DFX Tensile Tape suture is an uncoated braid offered in a variety of cut lengths, with or without needles, and provided sterile for single use only. Force DFX Tensile Tape suture is flat in shape and differs from USP requirements (not USP). It is available in 1.5mm, 2mm, tape width sizes and composed of undyed or blue Ultra High Molecular Weight Polyethylene (UHMWPE). Force DFX Tensile Tape suture sizes meet USP tensile strength requirements and USP needle attachment requirements for USP size #2 suture.

Identifier	Size & Construct	Color
DFX0020S	Force DFX Tensile Tape Braided White Size 2mm 30", C-7 Needle Taper Pt., 1/2C, 38.9mm	Composed of undyed (white) Ultra High Molecular Weight Polyethylene (UHMWPE).
DFX0021S	Force DFX Tensile Tape Braided White Size 2mm 18", C-7 Needle Taper Pt., 1/2C, 38.9mm	Composed of undyed (white) Ultra High Molecular Weight Polyethylene (UHMWPE).
DFX0022S	Force DFX Tensile Tape Braided Blue Size 2mm 30" C-7 ,Needle Taper Pt., 1/2C, 38.9mm	Composed of Ultra High Molecular Weight Polyethylene (UHMWPE). Blue: Color: chromium-cobalt-aluminum oxide <2% by weight
DFX0023S	Force DFX Tensile Tape Braided Blue Size 2mm 18" C-7, Needle Taper Pt., 1/2C, 38.9mm	Composed of Ultra High Molecular Weight Polyethylene (UHMWPE). Blue: Color: chromium-cobalt-aluminum oxide <2% by weight
DFX0024S	Force DFX Tensile Tape Braided White Size 1.5mm 30", HC-5 Needle 1/2 C, Taper Point, 25.9mm	Composed of undyed (white) Ultra High Molecular Weight Polyethylene (UHMWPE).
DFX0025S	Force DFX Tensile Tape Braided White Size 1.5mm 18" HC-5 Needle 1/2 C, Taper Point, 25.9mm	Composed of undyed (white) Ultra High Molecular Weight Polyethylene (UHMWPE).

DFX0026S	Force DFX Tensile Tape Braided Blue Size 1.5mm 30", HC-5 Needle 1/2 C, Taper Point, 25.9mm	Composed of Ultra High Molecular Weight Polyethylene (UHMWPE). Blue: Color: chromium-cobalt-aluminum oxide <2% by weight
DFX0027S	Force DFX Tensile Tape Braided Blue Size 1.5mm 18", HC-5 Needle 1/2 C, Taper Point, 25.9mm	Composed of Ultra High Molecular Weight Polyethylene (UHMWPE). Blue: Color: chromium-cobalt-aluminum oxide <2% by weight

6. **Indications for Use:** "The Dunamis Force DFX Tensile Tape Sutures are indicated for use in approximation and/or ligation of soft tissues including use of allograft tissue for orthopaedic surgeries".

7. **Identification of Risk Analysis:** The risk profile is identical to the risk analysis and profile generated by Teleflex Force Fiber Polyethylene Non-Absorbable Surgical Sutures, K150438. There are no changes or new concerns related to safety and effectiveness including biocompatibility, sterility, physical/performance characteristics, and clinical studies or labeling (other than brand name, part numbers and "manufactured for" indication).

8. **Discussion of the device characteristics**: The Dunamis device characteristics are identical to the Teleflex device characteristics as established in Teleflex 510k K150438 and as contract manufactured by Teleflex for Dunamis.

9. **Description of Device Design and Test Methods:** Dunamis LLc. has established a contract manufactured product specifications that has been accepted by Teleflex Medical which documents and secures the product configuration and required test methods to assure the device is equivalent in performance and to all the elements of Teleflex 510k K150438. Test Methods include:

    - Suture Average Width
    - Suture Average Height
    - Suture Length
    - Knot-Pull Tensile Strength
    - Needle Attachment Strength
    - Sterility test