



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

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

October 14, 2015

Re: K151220

Trade/Device Name: Dunamis Interference Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI  
Dated: May 1, 2015  
Received: May 7, 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" (21 CFR 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,

**Mark N. Melkerson -S**

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

Enclosure

# Indications for Use Form

## Indications for Use:

510(k) Number (if known): K151220

**Device Name:** Dunamis Interference Screw

The Dunamis Interference Screw are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameters of 9mm or less and a length of 25mm or less are also intended for use in the following procedures:

<p><b>Knee</b></p> <ul style="list-style-type: none"> <li>• ACL Repairs</li> <li>• PCL Repairs</li> <li>• Extra-capsular repairs               <ul style="list-style-type: none"> <li>– Medial collateral ligament</li> <li>– Lateral collateral ligament</li> <li>– Posterior oblique ligament</li> </ul> </li> <li>• Patellar realignment and tendon repairs               <ul style="list-style-type: none"> <li>– Vastus medialis obliquous advancement</li> </ul> </li> <li>• Iliotibial band tenodesis</li> </ul>	<p><b>Foot and Ankle</b></p> <ul style="list-style-type: none"> <li>• Hallux valgus repairs</li> <li>• Medial or lateral instability repairs/reconstructions</li> <li>• Achilles tendon repairs/reconstructions</li> <li>• Midfoot reconstructions</li> <li>• Metatarsal ligament/tendon repairs/reconstructions</li> <li>• Bunionectomy</li> <li>• Flexor Hullucis Longus (FLH)</li> <li>• Tendon Transfers</li> </ul>
<p><b>Shoulder</b></p> <ul style="list-style-type: none"> <li>• Capsular stabilization               <ul style="list-style-type: none"> <li>– Bankart repair</li> <li>– Anterior shoulder instability</li> <li>– SLAP lesion repairs</li> <li>– Capsular shift or capsulolabral reconstructions</li> </ul> </li> <li>• Acromioclavicular separation repairs</li> <li>• Deltoid repairs</li> <li>• Rotator cuff tear repairs</li> <li>• Biceps tenodesis</li> </ul>	<p><b>Elbow, Wrist, and Hand</b></p> <ul style="list-style-type: none"> <li>• Biceps tendon reattachment</li> <li>• Ulnar or radial collateral ligament reconstructions</li> <li>• Lateral epicondylitis repair</li> <li>• Scapholunate ligament reconstruction</li> <li>• Tendon Transfers</li> <li>• Carpometacarpal Joint Arthroplasty</li> <li>• Carpal Ligament Reconstruction</li> </ul>

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

## **Section 4 510(K) Summary of Safety and Effectiveness – R2**

Dunamis Interference Screw 8mm, 9mm, 10mm, 11mm x 25mm

Date Prepared: October 07, 2015

A. Submitters Name:

Dunamis, LLC.  
693 Sherling Lake Rd.  
Greenville, AL. 36037

B. Company Contact

Dr. Prithvi Raj Chavan  
Dunamis, LLC.  
693 Sherling Lake Rd.  
Greenville, AL. 36037  
334-239-0774  
www.Dunamismedical.com

C. Device Name

Trade Name: Dunamis Interference Screw  
Common Name: Screw, Fixation, Bone  
Classification Name: Smooth or threaded metallic bone fixation fastener  
Product Code: MBI  
Regulation Number: 21CFR888.3040

D. Predicate Devices: The Dunamis Interference Screw is substantially equivalent in Intended use and performance to the following legally marketed devices in commercial distribution: Smith & Nephew Biosure PK Interference Screw 510(k) K083635.

E. Description of Device

Reattachment of ligament, tendon, soft tissue, or bone to bone, shoulder, foot, ankle, knee, elbow and hand/wrist.

F. Intended Use:

The Dunamis Interference Screw are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less and a length of 25 mm or less are also intended for use in the following procedures:

**Knee**

- ACL Repairs
- PCL Repairs
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medialis obliquous advancement
- Iliotibial band tenodesis

### **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

### **Foot and Ankle**

- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy
- Flexor Hallucis Longus (FLH)
- Tendon Transfers

### **Elbow, Wrist, and Hand**

- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstructions
- Lateral epicondylitis repair
- Scapholunate ligament reconstruction
- Tendon Transfers
- Carpometacarpal Joint Arthroplasty
- Carpal Ligament Reconstruction

## G. Comparison of Technological Characteristics

The Dunamis Interference Screw is substantially equivalent in intended use, technological characteristics, and is safe and effective as its currently marketed predicate device, Smith & Nephew Biosure PK Interference Screw (K083635).

## H. Summary Performance Data

The performance testing conducted demonstrates that the insertion and fixation properties of the Dunamis Interference Screw are substantially equivalent to the Smith & Nephew Biosure PK Interference Screw (K083635).

### Overall Performance Testing includes:

- Torsional Yield Strength, Maximum Torque and Breaking Angle
- Insertion and Removal Torque
- Axial Push-Out Strength
- Self-Tapping force
- Biocompatibility
- Sterilization Validation
- Ethylene Oxide Residuals
- Sterile Barrier Packaging performance
- Aging of Sterile Medical Device