K083150 #1/2 JAN 15 2009

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the G-Force™ Tenodesis Screw.

Submitted By:	Wright Medical Technology, Inc.
Date:	October 6, 2008
Contact Person:	Kellen Hills Regulatory Affairs Specialist
Proprietary Name:	**G-FORCE™ Tenodesis Screw**
Common Name:	Interference Screw
Classification Name and Reference:	21 CFR 888.3040 Fastener, Fixation, Nondegradable, Soft Tissue – Class II
Device Product Code and Panel Code:	Orthopedics/87/MBI

DEVICE INFORMATION

A. INTENDED USE

Indications for the G-FORCE™ Tenodesis Screw include use in soft tissue reattachment procedures in the shoulder, foot/ankle, knee, elbow and wrist/hand where the sizes offered are patient appropriate. Specific indications include the following:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsule Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruction and tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

K083150

Wrist/Hand: Scapholunate Ligament Reconstruction, Ulnar/Radial Collateral Ligament Reconstruction, Carpometacarpal Joint Arthroplasty, Carpal Ligament Repair/Reconstruction and tendon transfers in the wrist and hand.

B. DEVICE DESCRIPTION

The design features of the G-FORCE™ Tenodesis Screw are described below.

- Generous thread radii to minimize soft tissue damage
- Manufactured from PEEK-Optima
- Radiolucent
- Screws are available in five diameters and four lengths

The design features of the G-FORCE™ Tenodesis Screw are substantially equivalent to the design features of other devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the G-Force™ Tenodesis Screw are substantially equivalent to previously cleared predicate devices. The safety and effectiveness of the G-Force™ Tenodesis Screw is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Mr. Kellen Hills
5677 Airline Road
Arlington, Tennessee 38002

JAN 15 2009

Re: K083150
Trade/Device Name: G-Force™ Tenodesis Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: October 23, 2008
Received: October 24, 2008

Dear Mr. Hills:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083150

Device Name: G-FORCE™ Tenodesis Screw

Indications For Use:

Indications for the G-FORCE™ Tenodesis Screw include use in soft tissue reattachment procedures in the shoulder, foot/ankle, knee, elbow and wrist/hand where the sizes offered are patient appropriate. Specific indications include the following:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsule Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruction and tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Wrist/Hand: Scapholunate Ligament Reconstruction, Ulnar/Radial Collateral Ligament Reconstruction, Carpometacarpal Joint Arthroplasty, Carpal Ligament Repair/Reconstruction and tendon transfers in the wrist and hand.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083150