8. 510(k) Summary

K133668

MAR - 3 2014

1. Applicant

Shoulder Options, Inc.
100 E. South Main St.
P.O. Box 1458
Waxhaw, NC 28173

Date Prepared: November 26, 2013

Contact Person: John Kapitan, CEO
Tel: (704)512-0000
Fax: (704)831-5316
Email: kapitan@shoulderoptions.com

2. Device Name

Common/Usual Name:	Cannulated Bone Screws and Washers Plate, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener Single/multiple component metallic bone fixation appliances and accessories
Trade Name:	AFT™ GTF System
Regulation Number:	888.3040 888.3030
Product Code:	HWC: Screw, Fixation, Bone HRS: Plate, Fixation, Bone
Classification:	II
Panel:	Orthopedic

3. Predicate Devices

The Shoulder Options AFT™ Greater Tuberosity Fracture System is substantially equivalent to the following devices:

510(k) Number	Device	Manufacturer
K121672	Shoulder Options AFT Proximal Humerus Fracture Plate	Shoulder Options
K963172	Synthes 4.5mm Cannulated Screw	Synthes
K052483	Synthes Spherical Washers	Synthes

4. Description of the Device

The AFT™ Greater Tuberosity Fracture System (AFT-GTF) consists of anatomically shaped plates which are fixated with 3.5mm or 4.5mm locking screws and 4.5mm diameter non-locking screws. 4.5mm Cannulated screws are provided to be used with or without 10mm washers. The anatomic plate contains multiple holes to allow for suturing. It is available in left and right configurations. The fasteners are available in various lengths. All components are manufactured from Ti-6Al-4V (ASTM F136). The components are provided non-sterile for single-use.

5. Indications for Use

The AFT™ Greater Tuberosity Cannulated Screws are intended for fracture fixation of long bones and long bone fragments.

The AFT™ Greater Tuberosity Fracture Plate is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

6. Summary of Performance Data

Geometric equivalence and engineering rationale is provided to demonstrate substantial equivalence.

7. Safety & Effectiveness

The AFT™ Greater Tuberosity Fracture System is substantially equivalent to the Shoulder Options Proximal Humerus Fracture Plate (K121672) and Synthes 4.5mm Cannulated Screw system (K963172, K052483). The devices have the same "Indications for Use," are available by prescription only, and are provided non-sterile for single-use only. Based on this and the design similarities, it can be concluded that the AFT™ Greater Tuberosity Fracture System is both a safe and effective device and is substantially equivalent to the predicate devices.

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, 2014

Shoulder Options, Inc.
Mr. John Kapitan
100 East South Main Street, PO Box 1458
Waxhaw, North Carolina 28173

Re: K133668
Trade/Device Name: AFT ™ Greater Tuberosity Fracture System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 23, 2013
Received: January 8, 2014

Dear Mr. Kapitan:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Vincen[redacted]evlin -S

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

Enclosure

7. Indications for Use Statement

510(k) Number (if known): K133668

Device Name: AFT™ Greater Tuberosity Fracture System

Indications for Use:

The AFT™ Greater Tuberosity Cannulated Screws are intended for fracture fixation of long bones and long bone fragments.

The AFT™ Greater Tuberosity Fracture Plate is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices