



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

TriMed, Incorporated
Mr. Michael Capellan
QA/RA Manager
27533 Avenue Hopkins
Santa Clarita, California 91355

January 29, 2016

Re: K151735

Trade/Device Name: TriMed Humeral Supracondylar Fixation 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: October 30, 2015
Received: November 2, 2015

Dear Mr. Capellan:

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,

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

510(k) Number (if known)

K151735

Device Name

TriMed Humeral Supracondylar Fixation System

Indications for Use (Describe)

The following fracture configurations may be applicable for treatment using the TriMed Humeral Supracondylar Plates and TriMed Humeral Supracondylar Nail Plates:

1. Fractures of the humerus amenable to nail plate, plate and/or screw fixation where the size, shape, and location of the fractured bone are appropriate for the specific implant(s) being used.
2. The TriMed Humeral Supracondylar Fixation System intramedullary nail plate, plates and associated screws are intended for use in fixation of fractures of the distal humerus.

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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**Traditional 510(k) Notification for the
TriMed Humeral Supracondylar Fixation System**

510(K) SUMMARY

SUBMITTER INFORMATION

- A. Company Name: TriMed, Inc.
- B. Company Address: 27533 Avenue Hopkins
Santa Clarita, CA 91355
- C. Company Phone: (661) 255-7406
- D. Company Contact: Michael Capellan

PREPARATION DATE

June 24, 2015

DEVICE IDENTIFICATION

- A. Device Trade Name: TriMed Humeral Supracondylar Fixation System
TriMed Medial Humeral Supracondylar Plates
TriMed Posterolateral Humeral Supracondylar Plates
TriMed Medial Humeral Supracondylar Nail Plate
TriMed Medial Humeral Supracondylar Nail
- B. Device Common Name: Bone plates
Nail plates
Bone screws
- C. Classification Name: Single/Multiple component metallic bone fixation
appliances and accessories
- D. Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
- E. Product Code: HRS, HWC
- F. Device Class: Class II
- G. Classification Panel: Orthopedic Devices

PREDICATE DEVICES

- A. Trade Name: TriMed Bone Plates, K060041.

Traditional 510(k) Notification for the TriMed Humeral Supracondylar Fixation System

DEVICE DESCRIPTION

General:

The TriMed Humeral Supracondylar Fixation System is a set of implants which are to be used as an aid to the treatment of certain types of fractures that lend themselves to the principle of nail plate, plate and/or screw fixation. Devices include Medial Humeral Supracondylar Plates, Posterolateral Supracondylar Plates, Medial Humeral Supracondylar Nail Plates, bone screws, and pins. Like every type of orthopaedic implants, it cannot be assumed to be uniformly effective without risk. Use of these implants is not a substitute for normal tissue healing. These implants are designed to provide additional constraint of movement of a fractured bone and are intended only as an aid to fix the fracture in place during the healing process.

Basic Design Features:

The TriMed Humeral Supracondylar Fixation System consists of implants designed for fixation of certain fractures. Variation in implant size, diameter, and shape are intended to allow the implants to accommodate variations in patient size and sites of application. These devices are manufactured from 316LS medical grade implant quality stainless steel. TriMed Humeral Supracondylar Plates and TriMed Supracondylar Nail Plates should only be used with the appropriate size TriMed Bone Screws and TriMed Supracondylar Nail Plate Interlocking Screws. As with interlocking nail plate and plate and screw fixation in general, the surgeon should take measures to avoid excessive force on implant until bone healing has taken place. This includes protection of the fracture when appropriate, and instructions to the patient to avoid excess loading of the extremity until sufficient healing has taken place.

Parts and Materials Provided:

Please see Attachment C – Bill of Materials

INTENDED USE

The TriMed Humeral Supracondylar Fixation system is intended for supracondylar fractures of the distal humerus that occur in the adolescent, adult and elderly population. This system is contraindicated for use in infants and small children because of size discrepancy.

Fractures of the distal humerus that require fixation and lend themselves to open surgical treatment are appropriate indications for use with these devices. This includes simple supracondylar fractures of the distal humerus, isolated medial or lateral column fractures of the distal humerus, T-condylar fractures of the distal humerus, and comminuted intra-articular fractures of the distal humerus are all appropriate indications for fixation with the TriMed Humeral Supracondylar Fixation System.

Selection of specific implants is determined by the physician based on the pattern of fracture. Screw fixation, lateral plating, medial plating, and intramedullary nail plate fixation can be used either alone or in combination depending on the nature of the injury.

Traditional 510(k) Notification for the TriMed Humeral Supracondylar Fixation System

Indications For Use:

The following fracture configurations may be applicable for treatment using the TriMed Humeral Supracondylar Plates and TriMed Humeral Supracondylar Nail Plates:

1. Fractures of the humerus amenable to nail plate, plate and/or screw fixation where the size, shape, and location of the fractured bone are appropriate for the specific implant(s) being used.
2. The TriMed Humeral Supracondylar Fixation System intramedullary nail plate, plates and associated screws are intended for use in fixation of fractures of the distal humerus.

COMPARISON TO PREDICATE DEVICES

The TriMed Humeral Supracondylar Fixation System is substantially equivalent in the following technological ways to the intended use and application in the identified predicate devices;

- Indications for Use
- Basic design
- Materials used
- Where used
- Standards met

TESTING AND PERFORMANCE DATA

Product Safety testing is not applicable.

Electromagnetic Compatibility and Immunity testing is not applicable.

No other specific guidance document on performance is required for this type of device.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Biocompatibility – Every implant mentioned above is made from 316LVM biocompatible stainless steel per standards ASTM-F138/ASTM-F139.

This material has a long history of use in implants, including the predicate device and many legally marketed devices within the same classification regulation and same intended use as this device. Further, no supplements or additives are used during the processing of the material and all implants are passivated per ASTM-F86 before and after lasermarking.

A Certificate of Biocompatibility is provided in Attachment J. Therefore, the biocompatibility of the TriMed Humeral Supracondylar Fixation System is based on FDA's clearance of the predicate TriMed device and the well-established history of the use of this material in similar applications.

Traditional 510(k) Notification for the TriMed Humeral Supracondylar Fixation System

Sterilization - No component of the TriMed Humeral Supracondylar Fixation System is provided sterile.

The sterilization procedure provided in the Recommendations for Sterilization section of the IMPORTANT MEDICAL INFORMATION document (Attachment B) has been validated by the North American Science Associates, Inc. (NAMSA) in their Northwood Ohio testing laboratory for the TriMed Fracture Fixation System (K040112). The test report which reflects testing completed by NAMSA is provided in Attachment G.

This sterilization procedure is applicable to the TriMed Humeral Supracondylar Fixation System because the System did not create a new worst-case sterilization scenario, as discussed in the Sterilization Equivalency Rationale, Attachment I.

Packaging – The complete Humeral Supracondylar Fixation System (implants and tools) is provided in a Sterilization Case. The case includes the company name and logo. Plus the device name: Humeral Supracondylar Fixation System.

Bench Testing - Transverse static and transverse bend moment testing was conducted on the TriMed Olecranon Hook Plate, the TriMed Semi Tubular Plate, and the plates from the TriMed Humeral Supracondylar Fixation system (HSFS), the Medial Humeral Supracondylar Plate, the Posterolateral Humeral Supracondylar Plates, and the Medial Humeral Supracondylar Nail Plate. This testing was conducted to verify that the strength of the TriMed HSFS is at least as high as the predicate devices.

As shown in the comparison table in the Substation Equivalence Discussion section, the transverse static failure load, the means of the failure loads of the plates in the TriMed HSFS far exceed the failure loads of the predicate devices. Further, the lowest failure load of any sample tested of the TriMed HSFS (the Medial Humeral Supracondylar Plate) is 85.0 pounds, versus the highest failure load for any sample of either predicate device is 73.3 pounds. This indicates that the transverse static strength of the TriMed HSFS is much greater than either of the predicate devices.

As shown in the comparison table in the Substation Equivalence Discussion section, the transverse bend moment at a .75 inch moment arm was far higher in the TriMed HSFS plates than in either of the predicate devices. Specifically, the TriMed Olecranon Hook Plate's bend moment was 50.9 inch-pounds, the TriMed Semi Tubular Plate's bend moment was 27.8 inch-pounds while the lowest of the three TriMed HSFS plates, the Medial Humeral Supracondylar Plate, had a bend moment of 70.1 inch pounds. Thus, the TriMed HSFS plates have a superior bend moment to either of the predicate devices.

Finally a computer analysis was conducted on both predicate devices and all three of the plates of the TriMed HSFS, as shown in the comparison table. This analysis of cross sectional strength showed superiority of the plates in the TriMed HSFS over both of the predicate devices.

See Attachment H for the Test Report.

**Traditional 510(k) Notification for the
TriMed Humeral Supracondylar Fixation System**

CONCLUSION

It is therefore the conclusion of TriMed that the Humeral Supracondylar Fixation System is substantially equivalent to devices already on the market [cleared by the 510(k) process] and presents no new concerns about safety and effectiveness.