



June 12, 2026

Tyber Medical, LLC  
Chelsea Smith  
Associate Director of Regulatory Affairs  
83 S. Commerce Way  
Suite 310  
Bethlehem, Pennsylvania 18017

Re: K261207

Trade/Device Name: Exalta Proximal Tibia Plating 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

Dated: April 13, 2026

Received: April 13, 2026

Dear Chelsea Smith:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Thomas Mcnamara -S**

For: Christopher Ferreira, M.S.

Assistant Director

DHT6C: Division of Restorative,  
Repair, and Trauma Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

# Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261207

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Please provide the device trade name(s).

?

Exalta Proximal Tibia Plating System

Please provide your Indications for Use below.

?

The Exalta Proximal Tibia Plating System is intended to bridge or otherwise stabilize bone fragments to facilitate healing. It is composed of the following indication categories:

I. Complete Articular – The Exalta Proximal Tibia Plating System is indicated for the treatment of nonunions, malunions, osteotomies, and fractures of the femur and tibia. This includes simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures, periprosthetic, and fractures with associated shaft fractures.

II. Partial Articular – The partial articular (also called buttress or anti-glide) proximal tibia plates are indicated for stabilization and reduction of proximal tibia fragments and treatment of partial articular fractures of the proximal tibia (AO/OTA Fracture Classifications Type B). The partial articular straight plates are indicated for stabilization and reduction of long bone fragments and partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classifications Type B), and for fracture fixation of the fibula.

III. Mini-Frag -- The Exalta Proximal Tibia Plating System is indicated for fixation of fractures, osteotomies, non-unions, replantations, and fusions of short bones and small bone fragments of bone, including, but not limited to, the hand, wrist, foot, and ankle. The Exalta Proximal Tibia Plating System is also intended for reduction and stabilization of non-load bearing long bone fragments. The Exalta Proximal Tibia Plating System is not for spinal use.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

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## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Tyber Medical LLC
Applicant Address	83 South Commerce Way, Suite 310 Bethlehem PA 18017 United States
Applicant Contact Telephone	267-671-7014
Applicant Contact	Mrs. Chelsea Smith
Applicant Contact Email	csmith@exalta.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Exalta Proximal Tibia Plating System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233017	TM Plating System	HRS
K090877	A.L.P.S. Proximal Tibia Plating System	HRS
K242486	Tyber Medical Anatomical Plating System	HRS

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

This traditional 510(k) is a line extension to the previously cleared TM Plating System under K233017. This submission updates the indications for use, and adds plates, screws, and instrumentation to the scope of the previous clearance.

The Exalta Proximal Tibia Plating System is a plating system designed to maintain fracture reduction and fixation for various types of fracture patterns that may occur in the proximal tibia region. The plates are manufactured from Ti-6Al-4V (ASTM F136) with a type II anodization, are offered in multiple lengths in left and right configurations and are anatomically contoured to fit anatomy in the lateral and medial aspects of the proximal tibia. Lateral plates are offered in standard and narrow widths. Medial plates are offered to fit direct medial, anteromedial, and posteromedial locations on proximal tibia.

All screw holes can accept either a locking or non-locking screw which were previously cleared in K242486. The screws are manufactured from Ti-6Al-4V (ASTM F136) with color anodization for sizing, are offered in multiple diameters and lengths.

The system also incorporates a specialized aiming arm that is specific to the Exalta Proximal Tibia System. Other ancillary instrumentation is available that is not specific to the system.

The Exalta Proximal Tibia Plating System is offered non-sterile.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Exalta Proximal Tibia Plating System is intended to bridge or otherwise stabilize bone fragments to facilitate healing. It is composed of the following indication categories:

I. Complete Articular – The Exalta Proximal Tibia Plating System is indicated for the treatment of nonunions, malunions, osteotomies, and fractures of the femur and tibia. This includes simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures, periprosthetic, and fractures with associated shaft fractures.

II. Partial Articular – The partial articular (also called buttress or anti-glide) proximal tibia plates are indicated for stabilization and reduction of proximal tibia fragments and treatment of partial articular fractures of the proximal tibia (AO/OTA Fracture Classifications Type B). The partial articular straight plates are indicated for stabilization and reduction of long bone fragments and partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classifications Type B), and for fracture fixation of the fibula.

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## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are similar to the predicate devices. The additional indications for use statement does not change the intended use of the Exalta Proximal Tibia Plating System. It is still intended to bridge or otherwise stabilize bone fragments to facilitate healing.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

A comparison of the subject device and predicate device demonstrated that the Exalta Proximal Tibia Plating System is substantially equivalent to the previously cleared TM Plating System (K233017). The Exalta Proximal Tibia Plating System has the same intended use and utilizes the same materials as the predicate devices. The Exalta Proximal Tibia Plating System has similar indications for use and technological characteristics.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

### Non Clinical Testing:

A comparative engineering analysis of the subject plates (per ASTM F382) and biocompatibility evaluation of all subject devices (per ISO 10993-1) was used to demonstrate substantial equivalence. The subject screws are identical to the previously cleared screws in K242486.

### Clinical Testing:

Not Applicable.

### Conclusions:

Based on the information contained in this submission, the Exalta Proximal Tibia Plating System is substantially equivalent to the predicate device.