April 10, 2026

Actis Medical Pty., Ltd.
% Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality, LLC
543 Long Hill Ave.,
Shelton, CT 06484

Re: K260090
Trade/Device Name: SMART Osteotomy 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 10, 2025
Received: January 12, 2026

Dear Joseph Azary :

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) 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.	K260090

Please provide the device trade name(s).

SMART Osteotomy System

Please provide your Indications for Use below.

The SMART Osteotomy plates are intended for use in open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia, medial distal femur and lateral distal femur, treatment of bone and joint deformities, fractures and malalignment caused by injury or disease such as osteoarthritis.

The system is intended for skeletally mature patients only.

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)

510(k) Summary
Traditional 510(k)
Orthopeasia Spinal Orthopedic Fixation System

1. SUBMITTER/510(K) HOLDER

Actis Medical Pty. Ltd
3/18 Ashwin Parade
Torrensville, South Australia
5031
Australia

Submission Contact

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Date Prepared: January 9, 2026

Reason for 510(k): New device / Initial Submission

2. DEVICE NAME

Proprietary Name:	SMART Osteotomy System
Classification Name:	Single / Multiple Component Metallic Bone Fixation Appliance and Accessories
Common Name:	Metallic Bone Fixation Appliance and Accessories
Classification Regulation:	21 CFR 888.3030
Product Code:	HRS
Secondary Product Codes:	HWC
Classification:	Class 2
Medical Specialty (Panel):	Orthopedic

3. PREDICATE DEVICES

Device Name	Manufacturer	510(k) Number
DePuy Synthes TOMOFIX Osteotomy System	Synthes (USA) Products LLC	K141796

4. DEVICE DESCRIPTION

The SMART Osteotomy system consists of profiled plates, designed to fit the proximal tibia or distal femur. Plates are anatomically shaped machined titanium, with holes for placement of screws that hold the plate to the bone. They are designed to be implanted on the surface of the proximal tibia or distal femur to stabilize the osteotomy gap, maintaining the correction angle until union. Bone screws fix the plate in position relative to the bone to locate fragments, reduce the fracture, and prevent the plate from shifting. Variable angle locking screws are fixed to the plate, preventing screw back-out. Non-locking screws compress the plate to the bone surface, featuring threads that penetrate deeper into cancellous bone.

The plates and screws are single use, terminally sterilized by the manufacturer via gamma radiation. The devices are packaged individually in a heat sealed inner Tyvek pouch then packaged in an heat sealed outer pouch, The double packaged device is placed inside a cardboard box that is labeled and shrink wrapped.

The devices are used with a standard armamentarium of reusable surgical instruments that are to be sterilized by the user.

5. INTENDED USE / INDICATIONS FOR USE

The SMART Osteotomy plates are intended for use in open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia, medial distal femur and lateral distal femur, treatment of bone and joint deformities, fractures and malalignment caused by injury or disease such as osteoarthritis.

The system is intended for skeletally mature patients only.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device has similar and/or identical characteristics as the predicate devices including material composition, principles of operation, similar indications for use, system components, configurations, tapered ends, holes for screws, similar sized screws, sterile, single use and standard armamentarium of instruments.

The minor differences are that the devices have different shaped heads and the dimensions of the subject device plates are slightly smaller compared to the predicate.

Substantial Equivalence Comparison Table

Technological Characteristic	**Subject Device**	**TOMOFIX K141796**	**Comparison**
Indications for Use	The SMART Osteotomy plates are intended for use in open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia, medial distal femur and lateral distal femur, treatment of bone and joint deformities, fractures and malalignment caused by injury or disease such as osteoarthritis. The system is intended for skeletally mature patients only.	The DePuy Synthes TOMOFIX Osteotomy System is intended for osteotomies, treatment of bone and join deformities, fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia. Specifically, The TOMOFIX Medial Proximal Tibia Plates are indicated for open and closed wedge osteotomies fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis , of the medial proximal tibia The TOMOFIX Lateral Proximal Tibia Plates are indicated for open and closed wedge osteotomies fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis , of the lateral proximal tibia The TOMOFIX Lateral Distal Femur Plates are indicated for open and closed wedge osteotomies fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis , of the	EQUIVALENT The devices are both used for treatment of bone and joint deformities, fixation of fractures and malalignment in Tibia and Femur.

		lateral distal femur The TOMOFIX Medial Distal Femur Plates are indicated for open and closed wedge osteotomies fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis , of the medial distal femur	
System Components	Plates and Screws Instruments	Plates and Screws Instruments	IDENTICAL
Configurations	Offered in Medial High Tibia Lateral High Tibia Medial Distal Femur Lateral Distal Femur	Offered in Medial High Tibia Lateral High Tibia Medial Distal Femur Lateral Distal Femur	IDENTICAL
Classification Regulation / Product Code	HRS Class II 21 CFR 888.3030	HRS Class II 21 CFR 888.3030	IDENTICAL
Material	Medical Grade Titanium Alloy	Medical Grade Titanium Alloy	IDENTICAL
Sterility	Plates and Screws are provided sterile using Gamma Radiation Instruments must be sterilized using steam sterilization by user	Plates and Screws are provided sterile using Gamma Radiation Instruments must be sterilized using steam sterilization by user	IDENTICAL
Single Use	Plates and Screws are Single Use	Plates and Screws are Single Use	IDENTICAL
Pediatric Usage	No, not indicated for pediatric usage	No, patients where growth plates have fused	IDENTICAL
Principles of Operation	Anatomically shaped plates with holes for placement of screws that hold the plate to the bone. They are designed to be implanted on the surface of the proximal tibia to stabilize the osteotomy gap,	Pre-contoured to fit the anatomy of the medial or lateral proximal tibia. Locked internal fixator providing angular stable fixation for osteotomy gap stabilization until union is achieved. The fixed-angle locking	IDENTICAL

	maintaining the correction angle until union. Bone screws fix the plate in position relative to the bone to locate fragments, reduce the fracture, and prevent the plate from shifting. Locking screws are fixed to the plate, preventing screw back-out. Non-locking screws compress the plate to the bone surface, featuring threads that penetrate deeper into cancellous bone.	holes provide multiple fixed-angle constructs throughout the plate, improving retention of screws in the plate and in cortical bone. Dynamic compression can be achieved by eccentric insertion titanium cortex screws in the dynamic compression unit portion of the hole.	
Shape	L-shaped locking compression plate Designed to bridge osteotomy gap with enough strength to maintain correction angle Tapered ends Plates able to accommodate both locking and compression screws	T-Shaped locking compression plate Design to bridge osteotomy gap with enough strength to maintain correction angle Tapered ends Plates have combi holes for either axial compression or locking capability	Devices have different shaped "heads", but all are design to match the anatomy.
Plate Dimensions	Lateral Distal Femur Plate: Length 103mm, width 32mm, Right and Left Lateral High Tibia Plate: Length 89mm, width 34mm, Right and Left Medial High Tibia Plate: Length 85.3mm, width 35mm, Right and Left Medial Distal Femur Plate: Length 102.5mm, width 29.6mm, Right and Left	Lateral Distal Femur Plate: Length 141mm, Right and Left Lateral High Tibia Plate: Length 102mm, Right and Left Medial High Tibia Head Plate: Length 112mm, Right and Left Medial Distal Femur Plate: Length 113.5mm, Right and Left	SIMILAR Both have plates for Lateral Distal Femur, Lateral High Tibia, Medial High Tibia and Medial Distal Femur The subject device has slightly shorter lengths compared to the predicate devices.
Screw Dimensions	Locking Screws Diameter 4.5mm, lengths: 29mm – 90mm	4.5mm diameter, non-locking Lengths 24, 26, 28, 30,	SIMILAR Both have screws with 4.5mm diameter and similar ranges of lengths.

	Non-Locking Screws Diameter 4.5mm, lengths 29mm to 60mm	32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52mm 4.5mm diameter, non-locking Lengths 14, 16, 18, 20, 22, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 76, 80, 85, 90mm 5.0mm diameter, locking Lengths 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 60, 65, 70, 75, 80 85 5.0 diameter, locking Lengths: 14, 16, 18, 20, 22, 90	
Instruments	Standard Armamentarium of Instruments Drills, Drill Guides, Depth Gage, Screwdriver, Bone Tamp	Standard Armamentarium of instruments Drills, Drill Guides, Depth Gages, Screwdriver, Bone Spreader, Guide Wire	EQUIVALENT

7. PERFORMANCE TESTING

The SMART Osteotomy System was subjected to a variety of testing including:

- Biocompatibility Evaluation per ISO 10993-1
- Sterilization Validation
- Cleaning Validation (for reusable instruments)
- Usability
- Stability / Shelf Life
- MRI evaluation
- Packaging testing
- Mechanical Testing per ASTM F543 and ASTM F382

8. SAFETY AND EFFICACY

The subject device has been tested to and complies with applicable consensus standards. All of the testing passed and there were no identified issues that would impact the safety, performance, or efficacy of the subject device.

9. CONCLUSION

The information presented supports substantial equivalence of the SMART Osteotomy System to the predicate device based on similarities in intended use, design, principles of operation and performance specifications.

The company concluded that based on testing, compliance to consensus standards, the indications for use, technological characteristics, and comparison to predicate device the SMART Osteotomy System found that the differences do not impact the ability of the devices to be safe and effective for their intended use.