



April 17, 2026

Medartis AG
Salvatore Risoli
Hochbergerstrasse 60E
Basel, 4057
Switzerland

Re: K260934

Trade/Device Name: TITAN Nail and APTUS K-Wire System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: March 16, 2026
Received: March 20, 2026

Dear Mr. Risoli:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.

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.

K260934

?

Please provide the device trade name(s).

?

TITAN Nail;
APTUS K-Wire System

Please provide your Indications for Use below.

?

TITAN Nail:
APTUS Cannulated Compression Screws and headed Cannulated Compression Screws, including TITAN Nails, are indicated for the treatment of fractures, osteotomies and arthrodesis of bones with the appropriate screw size.

APTUS K-Wire System:
APTUS K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

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](#))

?

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)

?

510(k) #: **K260934**

510(k) Summary

Prepared on: 2026-04-13

Contact Details

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

Applicant Name	Medartis AG
Applicant Address	Hochbergerstrasse 60E Basel 4057 Switzerland
Applicant Contact Telephone	+41797728067
Applicant Contact	Mr. Salvatore Risoli
Applicant Contact Email	Salvatore.Risoli@medartis.com

Device Name

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

Device Trade Name	TITAN Nail; APTUS K-Wire System
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code(s)	HWC, HTY

Legally Marketed Predicate Devices

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

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232251	APTUS Cannulated Compression Screws	HWC
K202589	APTUS K-Wire System	HTY

Device Description Summary

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

The purpose of this submission is to obtain marketing clearance for the subject device TITAN Nail and APTUS K-Wire System to expand the range of the Medartis APTUS fixation devices, previously cleared K232251, K133460, K110658 and K202589. The sterile TITAN Nail is available in three different system sizes for treatment of fractures, osteotomies and arthrodesis of bones. The sterile APTUS K-Wire System is available in two different diameters for fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

The subject device TITAN Nail is manufactured from titanium alloy conforming to ASTM F136, using the same manufacturing process as the predicate device and are cannulated, headless and fully threaded in design. They are available in lengths from 12mm to 80mm and diameters ranging from 2.2 to 4.0mm. TITAN Nail implants are offered sterile (X-ray beam sterilization).

The subject device APTUS K-Wire System is manufactured from stainless steel conforming to ASTM F138, using the same manufacturing process as the predicate device. They are available in length of 100mm and diameters of 0.8mm and 1.1mm and have a double-ended trocar. APTUS K-Wires are offered sterile (X-ray beam sterilization).

Intended Use/Indications for Use

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

TITAN Nail:
APTUS Cannulated Compression Screws and headed Cannulated Compression Screws, including TITAN Nails, are indicated for the treatment of fractures, osteotomies and arthrodesis of bones with the appropriate screw size.

APTUS K-Wire System:

APTUS K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

Indications for Use Comparison

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

The TITAN Nail has the same intended use and the same indications for use as the predicate device APTUS Cannulated Compression Screws cleared under K232251.

The APTUS K-Wire System has the same intended use and the same indications for use as the predicate device APTUS K-Wire System cleared under K202589.

Technological Comparison

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

TITAN Nail is substantially equivalent to the predicate device K232251 APTUS Cannulated Compression Screws. They share the same or similar technological characteristics, materials and dimensions.

APTUS K-Wire System is substantially equivalent to the predicate device K202589 APTUS K-Wire System. They share the same or similar technological characteristics, materials and dimensions.

Any differences do not raise new questions regarding safety or effectiveness. Overall, the TITAN Nail and APTUS K-Wire System have the following similarities to the predicate devices:

- have the same intended use,
- use the same operating principles,
- incorporate the same basic designs,
- incorporate similar materials, and
- are to be sterilized using the same materials and processes.

Non-Clinical and/or Clinical Tests Summary & Conclusions

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

An analysis of the risk documentation was performed. This determined that the original testing of the predicate devices K232251 and K202589 is not adversely affected by the modification described in this Special 510(k). Such modification does not introduce changes that affect the device's performance, safety, or effectiveness. A comprehensive design review determined that the modification is adequately evaluated by existing verification and validation (V&V) data. Because the modification does not impact the technological characteristics, performance specifications, or materials that form the basis for substantial equivalence to the predicate device, the existing non-clinical performance data remain applicable. Therefore, no additional non-clinical testing was required.

All design verification and validation activities were performed and confirm that the modified device continues to meet its design inputs and performance specifications.

The devices remain in conformity with all previously declared consensus standards within K232251 and K202589, as the modification does not impact performance attributes covered by these standards.

Clinical data is not provided in this submission.

Conclusion:

Based on the design-control impact assessment, existing verification and validation data, and unchanged compliance with applicable standards, no new non-clinical testing was required to support this Special 510(k) submission. The existing data continue to demonstrate that the modified device is substantially equivalent to the predicate device.