March 10, 2026

Reselute, Inc.
Brianna Prindle
Quality and Regulatory Head
701 W Main St.
Suite 410
Durham, North Carolina 27701

Re: K253517
Trade/Device Name: Reselute Tibial Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 18, 2026
Received: February 18, 2026

Dear Brianna Prindle:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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,

FARZANA SHARMIN -S

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.	K253517

Please provide the device trade name(s).

Reselute Tibial Nail

Please provide your Indications for Use below.

The Reselute Traditional Tibial Intramedullary Nail is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre and post isthmic fractures and tibial malunions and non-unions.

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)

Reselute

510(k) Summary

Date Prepared: March 10, 2025

The purpose of this submission is to seek clearance for a new device. This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. 510(k) Sponsor:

Reselute Medical
701 W Main St.
Suite 410
Durham, NC 27701

B. Primary Correspondent:

Brianna Prindle
Quality and Regulatory Consultant
brianna@reselutemedical.com
(786) 521-0501 (direct)

C. Premarket Notification:

Trade Name:	Reselute Tibial Nail
Regulation Name:	Intramedullary Fixation Rod
Common Name:	Rod, Fixation, Intramedullary And Accessories
Regulation Number:	21 CFR 888.3020
Product Code:	HSB
Classification:	II
Review Panel:	Orthopedic

D. Indications for Use:

The Reselute Tibial Intramedullary Nail is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre and post isthmic fractures and tibial malunions and non-unions.

E. Predicate Devices:

The Reselute Tibial Intramedullary Nail is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K143245	GPC Intramedullary Nailing Systems	GPC Medical Limited
Additional Predicate Device		
K230761	Trigen Meta Tibial Nail	Smith and Nephew

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F. Device Description:

The Reselute Tibial Intramedullary Nail System is a single use intramedullary device for the fixation, correction, or stabilization of the tibia. The Reselute Tibial Intramedullary Nail implant system includes a tibial nail offered at various diameters and lengths to accommodate a range of patient anatomies, cross-locking screws to prevent movement of the nail relative to the bone fragments, and optional endcaps for preventing proximal bone ingrowth. Each implant component is manufactured from titanium alloy (Ti-6Al-4V), which conforms to ASTM F136-13 for medical implants.

G. Comparison of Characteristics and Intended Use:

The subject Reselute Tibial Intramedullary Nail System is substantially equivalent to the primary predicate, GPC Intramedullary Nailing Systems (K143245) in material, design, technological characteristics, product features, and mechanical performance. The subject Reselute Tibial Intramedullary Nail System, primary predicate, and additional predicate, the Trigen Meta Tibial Nail, are all provided in similar sizing and manufactured from the same Ti-6Al-4V material per ASTM F136-13. The subject Reselute Tibial Intramedullary Nail System and primary predicate are provided with locking screws and endcaps.

The subject Reselute Tibial Intramedullary Nail System is substantially equivalent to the primary predicate, GPC Intramedullary Nailing Systems (K143245) in intended use and indications for use. The subject Reselute Tibial Intramedullary Nail System and primary predicate, the GPC Intramedullary Nailing Systems, are both intended for use for tibial fracture, tibial malunion and tibial non-unions. The subject and predicate device have identical indications for use.

H. Performance Testing:

The subject Reselute Tibial Intramedullary Nail System was subjected to the following mechanical performance tests to support the assertion of substantial equivalence:

- Static bending per ASTM F1264-16
- Static torsion per ASTM F1264-16
- Dynamic bending per ASTM F1264-16
- Dynamic screw bending per ASTM F1264-16
- Metallic bone screw testing per ASTM F543-23
- MR Testing per ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119

The results of this non-clinical testing demonstrate that the mechanical performance of the subject Reselute Tibial Intramedullary Nail System is sufficient for its intended use and no different questions of safety or efficacy were identified during device testing; therefore, the subject Reselute Tibial Intramedullary Nail System is considered substantially equivalent to the GPC Intramedullary Nailing Systems (K143245).

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I. Conclusions:

The Reselute Tibial Intramedullary Nail System was shown to be substantially equivalent in performance and has similar technological characteristics as the GPC Intramedullary Nailing Systems predicate through comparison in areas including design, intended use, implant materials, product features, mechanical performance, and function. Based on the data submitted, the Reselute Tibial Intramedullary Nail System does not raise any different questions about safety or efficacy. Therefore, the subject Reselute Tibial Intramedullary Nail System is considered substantially equivalent to the GPC Intramedullary Nailing Systems (K143245).