



June 27, 2025

Genostis AF
% Cheryl Wagoner
Principal Consultant/ Owner Wagoner Consulting LLC
Wagoner Consulting LLC
5215 Crosswinds Drive
Wilmington, North Carolina 28409

Re: K242988

Trade/Device Name: Genostis Osteosynthesis 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: May 23, 2025
Received: May 23, 2025

Dear Cheryl Wagoner:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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

510(k) Number (*if known*)
K242988

Device Name
Genostis Osteosynthesis System

Indications for Use (*Describe*)

Intended Use: Plate and screw Implants are intended for temporary fixation, correction or stabilization of bones in various anatomical regions.

One-Quarter Tubular Plates 2.4/2.7 are indicated for fixation of fractures of the foot, hand, wrist, and forearm (including radius). The plates should only be used for load-sharing purposes, e.g., buttressing, tension banding, neutralization, or compression.

Straight Plates 2.4/2.7 are indicated for fixation of fractures, osteotomies, malunions and nonunions of the foot, hand, wrist, and forearm (including radius) and arthrodesis of small bones of the foot and hand.

Reconstruction Plates 2.4/2.7 are indicated for fixation of fractures of the foot, hand, wrist, and forearm (including radius)

Radius Distal Styloid Plate 2.4/2.7 is indicated for the fixation for fractures of the radial styloid that have metaphyseal comminution or as an adjunct to either volar or dorsal plate fixation when additional support of the radial styloid is required.

The Radius Proximal head plates 2.4/2.7 are indicated for extra-articular and intra-articular fractures of the proximal radius and multifragmented radial neck fractures.

The Radius Distal Volar Plates 2.4/2.7 are indicated for the fixation for fractures, fusions, or osteotomies of the distal radius.

One-Third Tubular Plates 3.5 are indicated for fixation of fractures of the elbow (distal humerus and ulna), and fibula. The plates should only be used for load-sharing purposes, e.g., buttressing, tension banding, neutralization, or compression.

Reconstruction Plates 3.5 are indicated for fixation of fractures of the elbow (distal humerus and ulna), wrist, and forearm (including radius), fibula, and calcaneus

Straight Plates 3.5 are indicated for fixation of fractures, osteotomies, malunions and nonunions of the elbow (distal humerus and ulna), wrist, forearm (including radius), and fibula.

Tibia T-Plates 3.5 are indicated for buttressing of partial articular fractures and bone fragments of the distal tibia.

The Clavicle Superior Plates 3.5 are indicated for:

- Fractures of the clavicle shaft
- Fractures of the lateral clavicle
- Malunions of the clavicle
- Non-unions of the clavicle

The Clavicle Hook Plate 3.5 is indicated for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

The Humerus Proximal Plates 3.5 are indicated for the fixation of fractures, fracture dislocations, non-unions and osteotomies of the proximal humerus.

The Tibia Proximal Lateral Plates 3.5 are indicated for:

- Split-type fractures of the lateral tibial plateau
- Lateral split fractures with associated depressions
- Pure central depression fractures
- Split or depression fractures of the medial plateau

The Tibia Distal Medial Plates 3.5 are indicated for the fixation of fractures, osteotomies, and non-unions of the distal tibia.

The Tibia Distal Anterolateral Plates 3.5 are indicated for the fixation of fractures, osteotomies, and non-unions of the distal tibia.

The Humerus Distal Dorsolateral Plates 2.7/3.5 are indicated for

- Intraarticular fractures of the distal humerus
- Supracondylar fractures of the distal humerus
- Non-unions of the distal humerus

The Humerus Distal Medial Plates 2.7/3.5 are indicated for

- Intraarticular fractures of the distal humerus
- Supracondylar fractures of the distal humerus
- Non-unions of the distal humerus

The Ulna Proximal Olecranon Plates 3.5 are indicated for

- Complex extra- and intra-articular olecranon fractures
- Non-unions of the proximal ulna
- Osteotomies
- Simple olecranon fractures

Broad Curved Plates 4.5/5.0 are indicated for fixation of fractures, osteotomies, malunions and nonunions of humerus, femur, and tibia.

Broad Plates 4.5/5.0 are indicated for fixation of fractures, osteotomies, malunions and nonunions of humerus, femur, and tibia.

Narrow Plates 4.5/5.0 are indicated for fixation of fractures, osteotomies, malunions and nonunions of humerus, and distal tibia.

T Plate 4.5/5.0 is intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia. The plates should only be used for load-sharing purposes, e.g., buttressing, tension banding, neutralization, or compression.

T-Buttress Plates 4.5/5.0 are intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia.

The plates should only be used for load sharing purposes, e.g., buttressing, tension banding, neutralization, or compression.

LL-Buttress Plates 4.5/5.0 are intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia.

The plates should only be used for load sharing purposes, e.g., buttressing, tension banding, neutralization, or compression.

Femur Distal Plates 4.5/5.0 are indicated for distal shaft fractures, supracondylar fractures, intraarticular fractures, and periprosthetic fractures of the distal femur

Tibia Proximal Lateral Plates 4.5/5.0 are indicated for proximal shaft fractures, metaphyseal fractures, intra-articular fractures and periprosthetic fractures of the proximal tibia.

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.

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Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Genostis AG
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Applicant Contact	Dr. Sabine Söhndel
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Correspondent Contact	Mrs. Cheryl Wagoner
Correspondent Contact Email	cheryl@wagonerconsultingllc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Genostis Osteosynthesis System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	<u>888.3030</u>
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
K001945	Synthes LCP Low Bend Medial Distal Tibia Plates 3.5mm	HRS
K000682	Synthes 4.5 mm Narrow LCP Plates and 5.00 mm Locking Screws	HRS
K000684	Synthes LCP Olecranon Plate and Synthes 3.5 mm Locking Screws	HRS
K010321	Synthes Quarter Tubular Plate 2.7 with Collar	HRS
K010766	LCP L-Buttress Plates 4.5/5.0	HRS
K011335	Synthes 3.5 mm LCP one-third tubular plate	HRS

K030597	Synthes LCP Proximal Tibial Plate 3.5, Lateral	HRS
K033995	Synthes LCP Distal Humerus Plate , dorsolateral with support	HRS
K040777	Synthes LCP Proximal Radius Plates 2.4	HRS
K041911	Synthes 4.5 mm Curved Broad LCP Plates	HRS
K052390	Synthes LCP Proximal Lateral Tibia Plate 4.5/5.0	HRS
K061753	Synthes LCP Clavicle Hook Plate	HRS
K062564	Synthes LCP Distal Femur Plates	HRS
K063049	Synthes LCP plate 2.7 straight Synthes 2.4/2.7 mm locking screw	HRS
K073186	Synthes LCP Superior Clavicle Plate	HRS
K080522	Synthes 3.5 mm T Plate	HRS
K082625	Synthes PHILOS long-proximal diaphyseal humeral plate 3.5	HRS
K092812	Synthes LCP Anterolateral Distal Tibia Plate 3.5	HRS
K102998	Acumed Acu-Loc Plating System	HRS
K112583	Synthes 2.7/3.5 mm Cortex Screw	HWC
K161616	Synthes 4.5 mm Cortex Screw	HWC
K071715	Acumed Acu_LOC 2 Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Genostis Osteosynthesis System comprises of fracture fixation plates, corresponding screws and required surgical instruments. Different shapes and sizes are available to accommodate for different anatomical regions and locations of fractures. The plate screw interface is either locking, non-locking or, for some plates, realized by a combination hole offering both options (locking and non-locking).

All plates and screws are made of titanium alloy (Ti 6Al 4V ELI) according to ASTM F136 and ISO 5832-3.

The implants of the Genostis Osteosynthesis System are sterilized by radiation and are delivered sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications between the Subject device and its predicates are the same with minor wording differences.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject and predicate devices have the same technological characteristics including similar designs, materials, chemical composition and principle of operation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

This application includes biomechanical and biocompatibility testing per appropriate ISO and ASTM standards. All results were satisfactory. All standards are included in the standards section of this application.

Bacterial endotoxin testing was performed. Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), and Irritation/Intracutaneous reactivity (ISO 10993-23) were performed. Chemical characterization (ISO 10993-18) and toxicological risk assessment were also performed as part of the biocompatibility risk assessment. Screw performance testing per ASTM F543 and plate performance testing per ASTM F382 were performed.

All testing indicates that the Subject device is substantially equivalent to the predicates presented in this application. Each test was conducted on final sterile product.

For clarity, the buttress plates include: - One Third Tubular Plates 3.5, One Quarter Tubular Plates 2.4/2.7, Tibia T-Plate 3.5, T Plate 4.5/5.0, T- Buttress Plate 4.5/5.0, L – Buttress Plate 4.5/5.0