FDA 510(k) Premarket Notification

K242988 Genostis Osteosynthesis System

CLEARED

Jun 27, 2025
274 days to decision

K242988 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k242988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 26, 2024
Decision date	Jun 27, 2025
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Genostis AF**
Location	Burgdorf, CH
Contact	Sabine Söhndel
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Wagoner Consulting, LLC**
Contact	Cheryl Wagoner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov