FDA 510(k) Premarket Notification

K231292 TAMINA 3.5mm Proximal Humerus System

CLEARED

Jul 19, 2023
76 days to decision

K231292 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k231292/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 4, 2023
Decision date	Jul 19, 2023
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	POYA 3.5MM Lateral Proximal Tibia System; LORRAINE 3.5mm Distal Humerus System

APPLICANT

Company	**Bonebridge AG**
Location	Zug, CH
Contact	Michelle Gumpelmayer
510(k) history	9 submissions · 9 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Meditec Consulting GmbH**
Contact	Dawn Balazs-Metz

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