FDA 510(k) Premarket Notification

K254253 LOQTEQ® VA Proximal Humerus Plate 3.5

CLEARED

Mar 24, 2026
85 days to decision

K254253 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k254253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 29, 2025
Decision date	Mar 24, 2026
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aap Implantate AG**
Location	Berlin, DE
Contact	Andreas Reuter
510(k) history	37 submissions · 37 cleared · 1999-2026

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Kevin Thomas

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