

K211582 LOQTEQ Proximal Humerus Plate 3.5 SystemOct 18, 2021
150 days to decisionK211582 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k211582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 21, 2021
Decision date	Oct 18, 2021
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Melissa Burbage

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

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