

**K210043 LOQTEQ Distal Lateral Femur Plate 4.5 System**Mar 3, 2021  
55 days to decisionK210043 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k210043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 7, 2021
Decision date	Mar 3, 2021
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>PaxMed International, LLC</b>
Contact	Kevin A. Thomas

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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