FDA 510(k) Premarket Notification

K210043 LOQTEQ Distal Lateral Femur Plate 4.5 System

CLEARED

Mar 3, 2021
55 days to decision

K210043 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k210043/

SUBMISSION DETAILS

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

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	Kevin A. Thomas

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