

K200062 Foot and Ankle SystemFeb 22, 2021
406 days to decisionK200062 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k200062/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 13, 2020
Decision date	Feb 22, 2021
Days to decision	406 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Leith Medical, LLC
Location	Austin, TX, US
Contact	Tim Leak
510(k) history	1 submissions · 1 cleared · 2021-2021

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