

K200834 Lever Action Plate SystemJun 25, 2020
87 days to decisionK200834 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k200834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 30, 2020
Decision date	Jun 25, 2020
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mcginley Orthopaedic Innovations, LLC
Location	Casper, WY, US
Contact	Adam M. Johnson
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	David McGurl

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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