

K211646 FINE OsteotomyJul 28, 2021
61 days to decisionK211646 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k211646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 28, 2021
Decision date	Jul 28, 2021
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bodycad Laboratories, Inc.
Location	Quebec City, CA
Contact	Nadine Adia
510(k) history	16 submissions · 16 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	BioVera, Inc.
Contact	Robert A Poggie

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

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