FDA 510(k) Premarket Notification

K211646 FINE Osteotomy

CLEARED

Jul 28, 2021
61 days to decision

K211646 · 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