FDA 510(k) Premarket Notification

CLEARED

K200538 Skeletal Dynamics Forearm Plating System

Jun 1, 2020
90 days to decision

K200538 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k200538/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 3, 2020
Decision date	Jun 1, 2020
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Skeletal Dynamics, Inc.**
Location	Miami, FL, US
Contact	Diana Taylor
510(k) history	20 submissions · 20 cleared · 2020-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k200538/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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