FDA 510(k) Premarket Notification

K212782 SternaLock Sternal Closure System

CLEARED

May 17, 2022
258 days to decision

K212782 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k212782/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 1, 2021
Decision date	May 17, 2022
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Microfixation**
Location	Jacksonville, FL, US
Contact	Mark Wladkowski
510(k) history	24 submissions · 24 cleared · 2012-2024

REGULATORY CONSULTANT

Consulting firm	**MRC Global**
Contact	Christine Scifert

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