FDA 510(k) Premarket Notification

K202914 SternaFuse Fixation System

CLEARED

Jan 26, 2022
484 days to decision

K202914 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k202914/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 29, 2020
Decision date	Jan 26, 2022
Days to decision	484 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fusion Innovations, LLC**
Location	Rock Hill, SC, US
Contact	Mark Schumacher
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Kapstone Medical, LLC**
Contact	Katelyn Jessup

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202914/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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