FDA 510(k) Premarket Notification

K242939 ARTFX Trauma Bone Plate and Screw System

CLEARED

Dec 23, 2024
89 days to decision

K242939 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k242939/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 25, 2024
Decision date	Dec 23, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Artfx Medical**
Location	Jacksonville, FL, US
Contact	Ozgen Ozfidan
510(k) history	3 submissions · 3 cleared · 2024-2024