FDA 510(k) Premarket Notification

K242356 TIDAL Fusion Cage System

CLEARED

Mar 24, 2025
228 days to decision

K242356 · Product code: **SAI** · Orthopedic
Source: https://www.510kdatabase.net/k242356/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ankle Fusion Cage (SAI)
Date received	Aug 8, 2024
Decision date	Mar 24, 2025
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Restor3D, Inc.**
Location	Durham, NC, US
Contact	Brianna Prindle
510(k) history	6 submissions · 6 cleared · 2021-2025