FDA 510(k) Premarket Notification

K213590 Blue Topaz Sacroiliac Screw System

CLEARED

Mar 1, 2022
109 days to decision

K213590 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k213590/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Nov 12, 2021
Decision date	Mar 1, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osseus Fusion Systems, LLC**
Location	Round Rock, TX, US
Contact	Jonathan Rosen
510(k) history	5 submissions · 5 cleared · 2013-2022

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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