FDA 510(k) Premarket Notification

CLEARED

K223413 Pisces™-SA STANDALONE ALIF Interbody System

Feb 10, 2023
93 days to decision

K223413 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k223413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Nov 9, 2022
Decision date	Feb 10, 2023
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osseus Fusion Systems**
Location	Dallas, TX, US
Contact	Jonathan Rosen
510(k) history	5 submissions · 5 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical, LLC**
Contact	Jennifer Palinchik

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