FDA 510(k) Premarket Notification

K240830 Reef TO/TA System

CLEARED

Jun 20, 2024
86 days to decision

K240830 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k240830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 26, 2024
Decision date	Jun 20, 2024
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Regatta Lateral System; Explorer TO System; WaveForm C Interbody System; WaveForm TO Interbody System; WaveForm TA Interbody System; FORZA XP Expandable Spacer System; Shoreline ACS Interbody System; Shoreline RT Interbody System; Meridian Interbody System; WaveForm A Interbody System

APPLICANT

Company	**Orthofix Medical, Inc.**
Location	Lewisville, TX, US
Contact	Jesse Albright
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Justin Eggleton

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