FDA 510(k) Premarket Notification

K253420 Admiral ACP System

CLEARED

Jul 1, 2026
273 days to decision

K253420 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k253420/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 1, 2025
Decision date	Jul 1, 2026
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Explorer TO System; Laminoplasty System; Manta Ray TDF Spacer; Meridian Interbody System; Meridian Anterior Plate System; Reef L Interbody System; Reef TO/TA System; Regatta Lateral System; Regatta Lateral Plate System; Shoreline ACS Interbody System; Shoreline Threaded TruProfile Plate; Shoreline RT Interbody System; Vu Mesh; WaveForm A Interbody System; WaveForm C Interbody System; WaveForm L Interbody System; WaveForm TA Interbody System; WaveForm TO Interbody Sy

APPLICANT

Company	**SeaSpine Orthopedics Corporation**
Location	Carlsbad, CA, US
Contact	Kendal Moulton
510(k) history	67 submissions · 67 cleared · 2016-2026