FDA 510(k) Premarket Notification

K253291 Excelsior System

CLEARED

Jan 20, 2026
113 days to decision

K253291 · Product code: **KTT** · Orthopedic
Source: https://www.510kdatabase.net/k253291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Sep 29, 2025
Decision date	Jan 20, 2026
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Blue Ocean Global**
Location	Miami, FL, US
Contact	Scott Ludecker
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**MEDIcept, Inc.**
Contact	Danielle Short

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