

K253291 Excelsior SystemJan 20, 2026
113 days to decisionK253291 · 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	MEDlcept, Inc.
Contact	Danielle Short

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

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Device record: <https://www.510kdatabase.net/k253291/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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