

K153233 Galaxy UNYCO SystemJan 6, 2016
58 days to decisionK153233 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k153233/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Nov 9, 2015
Decision date	Jan 6, 2016
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix Srl
Location	Rockville, MD, US
Contact	GIANLUCA RICADONA
510(k) history	36 submissions · 36 cleared · 1995-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153233/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026