

K113770 ORTHOFIX GALAXY FIXATION SYSTEM

Sep 4, 2012
257 days to decision

K113770 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k113770/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Dec 22, 2011
Decision date	Sep 4, 2012
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k113770/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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