FDA 510(k) Premarket Notification

CLEARED

K173051 Orthofix MJ-FLEX THE NEW METAIZEAU NAIL

Nov 16, 2017
49 days to decision

K173051 · Product code: **HTY** · Orthopedic
Source: https://www.510kdatabase.net/k173051/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Sep 28, 2017
Decision date	Nov 16, 2017
Days to decision	49 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.net
Device record: https://www.510kdatabase.net/k173051/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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