

K160804 INTRAFIX(TM) Advance Tibial Fastener System

Jul 19, 2016
 118 days to decision

K160804 · Product code: **MAI** · Orthopedic
 Source: <https://www.510kdatabase.net/k160804/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Mar 23, 2016
Decision date	Jul 19, 2016
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medos International SARL
Location	Raynham, MA, US
Contact	KRISTINE CHRISTO
510(k) history	96 submissions · 96 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160804/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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