FDA 510(k) Premarket Notification

K083872 IMNS MEDACTA NAVIGATION SYSTEM

CLEARED

Jan 15, 2009
17 days to decision

K083872 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k083872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 29, 2008
Decision date	Jan 15, 2009
Days to decision	17 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Medacta International S.A.**
Location	Castel San Pietro, CH
Contact	NATLIE J KENNEL
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k083872/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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