FDA 510(k) Premarket Notification

K100314 IMNS MEDACTA NAVIGATION SYSTEM,33.221000US

CLEARED

Mar 31, 2010
55 days to decision

K100314 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k100314/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Feb 4, 2010
Decision date	Mar 31, 2010
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medacta International S.A.**
Location	Castel San Pietro, CH
Contact	HEATHER NEELY
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/k100314/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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