FDA 510(k) Premarket Notification

K101791 ROSA SURGICAL DEVICE

CLEARED

Sep 23, 2010
87 days to decision

K101791 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k101791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jun 28, 2010
Decision date	Sep 23, 2010
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtech S.A.S**
Location	Montpellier, FR
Contact	BERTIN NAHUM
510(k) history	3 submissions · 3 cleared · 2010-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k101791/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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