FDA 510(k) Premarket Notification

CLEARED

K092239 ROSA SURGICAL DEVICE, MODEL ROSA 1.1

Nov 17, 2009
117 days to decision

K092239 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k092239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jul 23, 2009
Decision date	Nov 17, 2009
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtech S.A**
Location	Montpellier, FR
Contact	BERTIN NAHUM
510(k) history	8 submissions · 8 cleared · 2009-2020