FDA 510(k) Premarket Notification

K100836 CLEARPOINT SYSTEM

CLEARED

Jun 16, 2010
84 days to decision

K100836 · Product code: **ORR** · Radiology
Source: https://www.510kdatabase.net/k100836/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument, Real-time Intraoperative Mri (ORR)
Date received	Mar 24, 2010
Decision date	Jun 16, 2010
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Surgivision, Inc.**
Location	Houston, TX, US
Contact	JOHN J SMITH M.D., J.D.
510(k) history	4 submissions · 4 cleared · 2009-2011