

K100836 CLEARPOINT SYSTEMJun 16, 2010
84 days to decisionK100836 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100836/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026