

K193147 Stereotaxis Genesis RMN with Navigant Workstation (NWS) and Cardiodrive SystemMar 5, 2020
113 days to decisionK193147 · Product code: **PJB** · Cardiovascular
Source: <https://www.510kdatabase.net/k193147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter Remote Control System (PJB)
Date received	Nov 13, 2019
Decision date	Mar 5, 2020
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stereotaxis, Inc.
Location	St. Louis, MO, US
Contact	Kenneth H. Lock
510(k) history	28 submissions · 28 cleared · 2002-2026

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