

K192775 Niobe® Magnetic Navigation System (MNS) with Navigant Workstation (NWS) and Cardiodri

Oct 30, 2019
30 days to decision

K192775 · Product code: **PJB** · Cardiovascular
Source: <https://www.510kdatabase.net/k192775/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter Remote Control System (PJB)
Date received	Sep 30, 2019
Decision date	Oct 30, 2019
Days to decision	30 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192775/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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