

K183027 Steerable catheter control systemSep 6, 2019
309 days to decisionK183027 · Product code: **PJB** · Cardiovascular
Source: <https://www.510kdatabase.net/k183027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter Remote Control System (PJB)
Date received	Nov 1, 2018
Decision date	Sep 6, 2019
Days to decision	309 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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