

**K994175 MODIFICATION TO SODEM HIGH SPEED SYSTEM
FOR NEUROSURGICAL USE**Dec 21, 1999
11 days to decisionK994175 · Product code: **HBB** · Neurology
Source: <https://www.510kdatabase.net/k994175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Motor, Drill, Pneumatic (HBB)
Date received	Dec 10, 1999
Decision date	Dec 21, 1999
Days to decision	11 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sodemsystems
Location	North Attleboro, MA, US
Contact	DANIEL BACCINO
510(k) history	8 submissions · 8 cleared · 1994-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994175/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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