

**K012457 SODEM HIGH SPEED SYSTEM (ELECTRIC)
(NEURO/SPINE SURGERY)**Oct 22, 2001
82 days to decisionK012457 · Product code: **HBC** · Neurology
Source: <https://www.510kdatabase.net/k012457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Motor, Drill, Electric (HBC)
Date received	Aug 1, 2001
Decision date	Oct 22, 2001
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012457/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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