

**K954717 SODEM HIGH SPEED SYSTEM FOR NEUROSURGERY
& MEDIAN STERNOTOMY**

Jan 22, 1997
467 days to decision

K954717 · Product code: **HBB** · Neurology
Source: <https://www.510kdatabase.net/k954717/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Motor, Drill, Pneumatic (HBB)
Date received	Oct 13, 1995
Decision date	Jan 22, 1997
Days to decision	467 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sodem Diffusion SA
Location	North Attleboro, MA, US
Contact	ROSINA ROBINSON
510(k) history	3 submissions · 3 cleared · 1995-1997

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Device record: <https://www.510kdatabase.net/k954717/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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