

K082127 STRATA NSC BURR HOLE VALVE, MODEL 42335Aug 27, 2008
29 days to decisionK082127 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k082127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Jul 29, 2008
Decision date	Aug 27, 2008
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary
Other names	SHUNT ASSEMBLY, MODEL 46635

APPLICANT

Company	Medtronic Neurosurgery
Location	Goleta, CA, US
Contact	JEFFREY HENDERSON
510(k) history	28 submissions · 27 cleared · 2001-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082127/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026