

K853368 H-H SHUNT INTRODUCERSep 6, 1985
25 days to decisionK853368 · Product code: **GYK** · Neurology
Source: <https://www.510kdatabase.net/k853368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Shunt System Implantation (GYK)
Date received	Aug 12, 1985
Decision date	Sep 6, 1985
Days to decision	25 days
Third-party review	No

APPLICANT

Company	Holter-Hausner Intl.
Location	Mchenry, IL, US
Contact	JOHN R BOLLES
510(k) history	42 submissions · 38 cleared · 1978-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853368/>; 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 22, 2026