FDA 510(k) Premarket Notification

K853368 H-H SHUNT INTRODUCER

CLEARED

Sep 6, 1985
25 days to decision

K853368 · 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