

**K101889 DECOMPRESSION OF CHOICE AND NEURO
DECOMPRESSION DEVICE**Aug 27, 2010
51 days to decisionK101889 · Product code: ITH · Physical Medicine
Source: <https://www.510kdatabase.net/k101889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Equipment, Traction, Powered (ITH)
Date received	Jul 7, 2010
Decision date	Aug 27, 2010
Days to decision	51 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Pivotal Health Solutions
Location	Watertown, SD, US
Contact	PHILLIP KLEIN
510(k) history	2 submissions · 2 cleared · 2010-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101889/> 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 June 6, 2026