

K110858 LO-BAK TRAXAug 2, 2011
127 days to decisionK110858 · Product code: **HST** · Neurology
Source: <https://www.510kdatabase.net/k110858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Traction, Non-powered (HST)
Date received	Mar 28, 2011
Decision date	Aug 2, 2011
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roland F Berthiaume, DC
Location	Springfield, MA, US
Contact	ROLAND F BERTHIAUME
510(k) history	1 submissions · 1 cleared · 2011-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110858/> 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 18, 2026