

K161835 iovera systemMar 24, 2017
262 days to decisionK161835 · Product code: **GXH** · Neurology
Source: <https://www.510kdatabase.net/k161835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Surgical, Cryogenic (GXH)
Date received	Jul 5, 2016
Decision date	Mar 24, 2017
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Myoscience, Inc.
Location	Redwood City, CA, US
Contact	Tracey Henry
510(k) history	9 submissions · 9 cleared · 2009-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161835/> 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 31, 2026