FDA 510(k) Premarket Notification

K161835 iovera system

CLEARED

Mar 24, 2017
262 days to decision

K161835 · 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