FDA 510(k) Premarket Notification

CLEARED

K153041 Bundled Neurological Shunts and Accessories Product Families Labeling Modification to Support MR Conditional Labeling

Mar 14, 2016
147 days to decision

K153041 · Product code: **JXG** · Neurology
Source: https://www.510kdatabase.net/k153041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Oct 19, 2015
Decision date	Mar 14, 2016
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Integra LifeSciences Corporation**
Location	Planisboro, NJ, US
Contact	Timothy Connors
510(k) history	65 submissions · 65 cleared · 2004-2025