

K130557 NEURAGEN 3DApr 24, 2014
416 days to decisionK130557 · Product code: **JXI** · Neurology
Source: <https://www.510kdatabase.net/k130557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Nerve (JXI)
Date received	Mar 4, 2013
Decision date	Apr 24, 2014
Days to decision	416 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Integra LifeSciences Corporation
Location	Planisboro, NJ, US
Contact	STEPHEN H BEIER
510(k) history	65 submissions · 65 cleared · 2004-2025

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