FDA 510(k) Premarket Notification

K131184 INTEGRA LICOX PTO2 MONITOR

CLEARED

Aug 30, 2013
127 days to decision

K131184 · Product code: **GWM** · Neurology
Source: https://www.510kdatabase.net/k131184/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Apr 25, 2013
Decision date	Aug 30, 2013
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Integra Lifesciences Corp.**
Location	Somerville, NJ, US
Contact	ELIZABETH MCMENIMAN
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510(k) history	29 submissions · 29 cleared · 1999-2019