FDA 510(k) Premarket Notification

K162108 Pressio 2 ICP Monitoring System

CLEARED

Apr 17, 2017
262 days to decision

K162108 · Product code: **GWM** · Neurology
Source: https://www.510kdatabase.net/k162108/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Jul 29, 2016
Decision date	Apr 17, 2017
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sophysa SA**
Location	Wellesley, MA, US
Contact	Jean-Christophe Audras
510(k) history	9 submissions · 9 cleared · 2000-2017