FDA 510(k) Premarket Notification

K101133 SENSOMETRICS SOFTWARE

CLEARED

Nov 18, 2010
210 days to decision

K101133 · Product code: **GWM** · Neurology
Source: https://www.510kdatabase.net/k101133/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Apr 22, 2010
Decision date	Nov 18, 2010
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dpcom AS**
Location	Ne, MN, US
Contact	CONSTANCE BUNDY
510(k) history	1 submissions · 1 cleared · 2010-2010