FDA 510(k) Premarket Notification

CLEARED

K102077 MODIFICATION TO CMA CEREBRAL TISSUE MONITORING SYSTEM

Jan 14, 2011
175 days to decision

K102077 · Product code: **GWM** · Neurology
Source: https://www.510kdatabase.net/k102077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Jul 23, 2010
Decision date	Jan 14, 2011
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cma Microdialysis AB**
Location	North Attleboro, MA, US
Contact	NANCY BLANCO
510(k) history	4 submissions · 4 cleared · 2002-2011