FDA 510(k) Premarket Notification

K161010 HICP200 Patient/Monitor Interconnect Cable

CLEARED

Oct 20, 2016
192 days to decision

K161010 · Product code: **GWM** · Neurology
Source: https://www.510kdatabase.net/k161010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Apr 11, 2016
Decision date	Oct 20, 2016
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innerspace Neuro Solutions, Inc.**
Location	Tustin, CA, US
Contact	Gary G. Frugard
510(k) history	1 submissions · 1 cleared · 2016-2016