

K152670 DirectLink ICP Module, DirectLink ICP Extension Cable, Patient Monitor Interface Cables

Jan 22, 2016
127 days to decision

K152670 · Product code: **GWM** · Neurology
Source: <https://www.510kdatabase.net/k152670/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Sep 17, 2015
Decision date	Jan 22, 2016
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medos International SARL
Location	Raynham, MA, US
Contact	Elena Jugo
510(k) history	96 submissions · 96 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152670/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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