

K223438 TELIGEN System Peripheral Motor Nerve Stimulation IndicationsFeb 10, 2023
88 days to decisionK223438 · Product code: **PDQ** · Neurology
Source: <https://www.510kdatabase.net/k223438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Nov 14, 2022
Decision date	Feb 10, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Synthes GmbH
Contact	Daria Bochenek

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026