FDA 510(k) Premarket Notification

K201454 DSG Connect Technology

CLEARED

Feb 10, 2021
254 days to decision

K201454 · Product code: **PDQ** · Neurology
Source: https://www.510kdatabase.net/k201454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Jun 1, 2020
Decision date	Feb 10, 2021
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spineguard S.A.**
Location	Washington, DC, US
Contact	Stephane Bette
510(k) history	6 submissions · 6 cleared · 2013-2022

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov