

K191687 pORTAL Steerable Hydrophilic Guidewire and pORTAL EXT Extension Wire

Oct 9, 2019
107 days to decision

K191687 · Product code: **DQX** · Neurology
Source: <https://www.510kdatabase.net/k191687/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 24, 2019
Decision date	Oct 9, 2019
Days to decision	107 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Phenox Limited
Location	Galway, IE
Contact	Gary Brogan
510(k) history	4 submissions · 4 cleared · 2019-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191687/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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