FDA 510(k) Premarket Notification

CLEARED

K193548 Mirage Hydrophilic Guidewire, X-pedion Hydrophilic Guidewire

Jan 18, 2020
29 days to decision

K193548 · Product code: **DQX** · Neurology
Source: https://www.510kdatabase.net/k193548/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 20, 2019
Decision date	Jan 18, 2020
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Micro Therapeutics, Inc. d/b/a ev3 Neurovascular**
Location	Lrvine, CA, US
Contact	Ryan Kenney
510(k) history	32 submissions · 32 cleared · 2014-2025