FDA 510(k) Premarket Notification

K220331 091 Balloon Guide Catheter

CLEARED

Jul 29, 2022
175 days to decision

K220331 · Product code: **DQY** · Neurology
Source: https://www.510kdatabase.net/k220331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 4, 2022
Decision date	Jul 29, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inneuroco, Inc.**
Location	Sunrise, FL, US
Contact	Marc Litzenberg
510(k) history	9 submissions · 9 cleared · 2016-2023