FDA 510(k) Premarket Notification

K200120 LiteSaber Wire Torque Assist Device

CLEARED

May 7, 2020
107 days to decision

K200120 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k200120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 21, 2020
Decision date	May 7, 2020
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vesatek, LLC**
Location	Irvine, CA, US
Contact	David Look
510(k) history	2 submissions · 2 cleared · 2017-2020