FDA 510(k) Premarket Notification

K201720 LiPPS Analyzer, LiPPS Wire Pressure Guide Wire

CLEARED

Feb 18, 2021
240 days to decision

K201720 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k201720/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 23, 2020
Decision date	Feb 18, 2021
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Bywave Sensing Medical Technology Co., Ltd.**
Location	Beijing, CN
Contact	Lizhe Zhang
510(k) history	1 submissions · 1 cleared · 2021-2021