FDA 510(k) Premarket Notification

K211530 PathBuilder Steerable Introducer

CLEARED

Feb 8, 2022
267 days to decision

K211530 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k211530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 17, 2021
Decision date	Feb 8, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Microport EP Medtech Co., Ltd.**
Location	Shanghai, CN
Contact	Tian Xia
510(k) history	4 submissions · 4 cleared · 2022-2022