FDA 510(k) Premarket Notification

K212625 PathBuilder Transseptal Needle

CLEARED

Mar 23, 2022
217 days to decision

K212625 · Product code: **DRC** · Cardiovascular
Source: https://www.510kdatabase.net/k212625/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Aug 18, 2021
Decision date	Mar 23, 2022
Days to decision	217 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