FDA 510(k) Premarket Notification

K242248 Introducer Sheath Kits

CLEARED

Aug 22, 2024
22 days to decision

K242248 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k242248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 31, 2024
Decision date	Aug 22, 2024
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Beijing Demax Medical Technology Co.,Ltd**
Location	Guangzhou, CN
Contact	Nicole Liu
510(k) history	4 submissions · 4 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Hlongmed Biotech Co., Ltd.**
Contact	Long Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov