FDA 510(k) Premarket Notification

CLEARED

K230283 Peel-Away Introducer (405104, 405108, 405112, 405116, 405118, 405119, 405120, 405122, 405124, 405128, 405129, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405269, 405270, 405404, 405408, 405412, 405416, 405418, 405420, 405422, 405424, 405428)

Mar 1, 2023
28 days to decision

K230283 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k230283/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Feb 1, 2023
Decision date	Mar 1, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Medical**
Location	S,Mta Clara, CA, US
Contact	Chidalu Mozie
Website	https://www.abbott.com
510(k) history	57 submissions · 57 cleared · 2019-2026

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...