FDA 510(k) Premarket Notification

K182064 ExpanSure Transseptal Dilation System

CLEARED

Mar 21, 2019
232 days to decision

K182064 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k182064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 1, 2018
Decision date	Mar 21, 2019
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Baylis Medical Company, Inc.**
Location	Mississauga, Ontario, CA
Contact	May Tsai
510(k) history	24 submissions · 24 cleared · 2012-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k182064/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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