FDA 510(k) Premarket Notification

K201288 ExpanSure Large Access Transseptal Dilator

CLEARED

Jun 12, 2020
29 days to decision

K201288 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k201288/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	May 14, 2020
Decision date	Jun 12, 2020
Days to decision	29 days
Third-party review	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