

K210627 Breezeway IIJun 3, 2021
93 days to decisionK210627 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k210627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 2, 2021
Decision date	Jun 3, 2021
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oscor, Inc.
Location	Palm Harbor, FL, US
Contact	Doug Myers
510(k) history	49 submissions · 46 cleared · 1979-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210627/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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