FDA 510(k) Premarket Notification

# K210627 Breezeway II

**CLEARED**

Jun 3, 2021
93 days to decision

K210627 · Product code: **DYB** · Cardiovascular
Source: 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 |