FDA 510(k) Premarket Notification

CLEARED

K140917 INTRODUCER, MODEL ADELANTE MAGNUM

Jul 9, 2014
90 days to decision

K140917 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k140917/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 10, 2014
Decision date	Jul 9, 2014
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k140917/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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