FDA 510(k) Premarket Notification

K090114 MODIFICATION TO:INTRODUCER SETS, MODEL ADELANTE AND ADELANTE-S

CLEARED

Jun 4, 2009
134 days to decision

K090114 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k090114/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jan 21, 2009
Decision date	Jun 4, 2009
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k090114/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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