FDA 510(k) Premarket Notification

K221464 CorPath GRX System

CLEARED

Jul 27, 2022
69 days to decision

K221464 · Product code: **DXX** · Cardiovascular
Source: https://www.510kdatabase.net/k221464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Catheter Control, Steerable (DXX)
Date received	May 19, 2022
Decision date	Jul 27, 2022
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corindus, Inc.**
Location	Baltimore, MD, US
Contact	Robert Lavado
510(k) history	9 submissions · 9 cleared · 2012-2022