FDA 510(k) Premarket Notification

K984214 CORDIS ENDOVASCULAR TEMPORARY OCCLUSION BALLOON CATHETER

CLEARED

Aug 10, 1999
259 days to decision

K984214 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k984214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Nov 24, 1998
Decision date	Aug 10, 1999
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Neurovascular, Inc.**
Location	Miami Lakes, FL, US
Contact	ALINA CARABALLO
510(k) history	37 submissions · 37 cleared · 1994-2008