FDA 510(k) Premarket Notification

K140185 OCELOT CATHETER, OCELOT PIXL CATHETER, LIGHTBOX CONSOLE

CLEARED

May 1, 2014
97 days to decision

K140185 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k140185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jan 24, 2014
Decision date	May 1, 2014
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avinger, Inc.**
Location	Redwood City, CA, US
Contact	SHERRY KIM
510(k) history	25 submissions · 25 cleared · 2009-2023