FDA 510(k) Premarket Notification

K160013 Crosperio OTW

CLEARED

Apr 29, 2016
116 days to decision

K160013 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k160013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jan 4, 2016
Decision date	Apr 29, 2016
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**KANEKA Corporation**
Location	Tokyo, JP
Contact	TOSHIHIKO MOTOMINE
510(k) history	10 submissions · 10 cleared · 2015-2018