FDA 510(k) Premarket Notification

K152873 Crosstella RX Balloon Dilatation Catheter

CLEARED

Jan 22, 2016
114 days to decision

K152873 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k152873/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Sep 30, 2015
Decision date	Jan 22, 2016
Days to decision	114 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