FDA 510(k) Premarket Notification

K123358 PACIFIC PLUS

CLEARED

Jan 29, 2013
90 days to decision

K123358 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k123358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Oct 31, 2012
Decision date	Jan 29, 2013
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	DIANA JOHNSON
510(k) history	475 submissions · 453 cleared · 1977-2023