FDA 510(k) Premarket Notification

CLEARED

K162625 SeQuent Neo Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheters

Jun 12, 2017
265 days to decision

K162625 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k162625/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Sep 20, 2016
Decision date	Jun 12, 2017
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**B. Braun Interventional Systems, Inc.**
Location	Minneapolis, MN, US
Contact	PETER FLOSDORF
510(k) history	3 submissions · 3 cleared · 2013-2017