FDA 510(k) Premarket Notification

K180921 Sapphire II PRO Balloon Dilatation Catheter

CLEARED

Jun 28, 2018
80 days to decision

K180921 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k180921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Apr 9, 2018
Decision date	Jun 28, 2018
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orbusneich Medical Trading, Inc.**
Location	Fort Lauderdale, FL, US
Contact	John Pazienza
510(k) history	7 submissions · 7 cleared · 2018-2020