FDA 510(k) Premarket Notification

K103808 SAPPHIRE NC

CLEARED

Sep 1, 2011
246 days to decision

K103808 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k103808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 29, 2010
Decision date	Sep 1, 2011
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orbusneich Medical, Inc.**
Location	Fort Lauderdale, FL, US
Contact	JOHN PAZIENZA
510(k) history	4 submissions · 4 cleared · 2011-2017