FDA 510(k) Premarket Notification

K203623 StentBoost Mobile

CLEARED

Apr 5, 2021
115 days to decision

K203623 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k203623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 11, 2020
Decision date	Apr 5, 2021
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips India Limited**
Location	Pune, IN
Contact	Shruti Sancheti
510(k) history	2 submissions · 2 cleared · 2017-2021