

K203623 StentBoost MobileApr 5, 2021
115 days to decisionK203623 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203623/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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