FDA 510(k) Premarket Notification

K171055 Philips BlueControl

CLEARED

Jul 6, 2017
87 days to decision

K171055 · Product code: **ONE** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k171055/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument (ONE)
Date received	Apr 10, 2017
Decision date	Jul 6, 2017
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Electronics Nederland B.V.**
Location	Eindhover, NL
Contact	Gaozhen Hang
510(k) history	2 submissions · 2 cleared · 2017-2019