FDA 510(k) Premarket Notification

K230905 OrthoPulse 2.0E (OPi2E-100)

CLEARED

Jun 9, 2023
70 days to decision

K230905 · Product code: **PLH** · Dental
Source: https://www.510kdatabase.net/k230905/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthodontic Led Accessory (PLH)
Date received	Mar 31, 2023
Decision date	Jun 9, 2023
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biolux Technology GmbH**
Location	Absdorf, AT
Contact	Daniela Penn
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230905/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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