FDA 510(k) Premarket Notification

K232076 Fibercure

CLEARED

Nov 2, 2023
112 days to decision

K232076 · Product code: **QNF** · Dental
Source: https://www.510kdatabase.net/k232076/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser Activator For Polymerization (QNF)
Date received	Jul 13, 2023
Decision date	Nov 2, 2023
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lumendo AG**
Location	Renens, CH
Contact	Mark Bispinghoff
510(k) history	2 submissions · 2 cleared · 2023-2023