FDA 510(k) Premarket Notification

K231387 Endofill

CLEARED

Jul 10, 2023
59 days to decision

K231387 · Product code: **KIF** · Dental
Source: https://www.510kdatabase.net/k231387/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	May 12, 2023
Decision date	Jul 10, 2023
Days to decision	59 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