FDA 510(k) Premarket Notification

K223470 C50

CLEARED

Dec 14, 2023
392 days to decision

K223470 · Product code: **NBL** · Dental
Source: https://www.510kdatabase.net/k223470/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Fluorescence Caries Detection (NBL)
Date received	Nov 17, 2022
Decision date	Dec 14, 2023
Days to decision	392 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sopro**
Location	Marseille, FR
Contact	Kim Rouahi
Website	http://www.soprole.cl/
510(k) history	25 submissions · 25 cleared · 1997-2023

Sopro specialized in surgical visualization and imaging devices for general and plastic surgery applications. The company operated a manufacturing facility in Marseille, France. Sopro received FDA 510(k) clearances from total submissions between 1997 and 2023. The company focused exclusively on General & Plastic Surgery devices, particularly endoscopy cameras, digital operating room cameras, and light source systems. All submissions resulted in clearance with no denials on record. The company's product portfolio included digital endoscopy cameras, laparoscopes, operating ...