

K121685 SOPROCAREMar 12, 2013
278 days to decisionK121685 · Product code: **NBL** · Dental
Source: <https://www.510kdatabase.net/k121685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Fluorescence Caries Detection (NBL)
Date received	Jun 7, 2012
Decision date	Mar 12, 2013
Days to decision	278 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sopro
Location	Marseille, FR
Contact	RICK ROSATI
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 ...
