FDA 510(k) Premarket Notification

K012505 SOPRO595 INTRA ORAL CAMERA

CLEARED

Oct 5, 2001
63 days to decision

K012505 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k012505/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Aug 3, 2001
Decision date	Oct 5, 2001
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sopro**
Location	Marseille, FR
Contact	PIERRE MONTILLOT
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 ...