FDA 510(k) Premarket Notification

K092329 SOPIX 2

CLEARED

Jul 20, 2010
350 days to decision

K092329 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k092329/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Aug 4, 2009
Decision date	Jul 20, 2010
Days to decision	350 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 ...