FDA 510(k) Premarket Notification

K072912 SOPRO 225 DUAL HALOGEN LIGHT SOURCE

CLEARED

Nov 16, 2007
35 days to decision

K072912 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k072912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Oct 12, 2007
Decision date	Nov 16, 2007
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sopro**
Location	Marseille, FR
Contact	STEVE SALESKY
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 ...