FDA 510(k) Premarket Notification

CLEARED

K070783 SOPRO MODEL 640 LAPAROSCOPIC INSUFFLATOR

Dec 13, 2007
267 days to decision

K070783 · Product code: **HIF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k070783/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Mar 21, 2007
Decision date	Dec 13, 2007
Days to decision	267 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 ...