

K031593 SOPRO 61DSep 16, 2003
118 days to decisionK031593 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k031593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	May 21, 2003
Decision date	Sep 16, 2003
Days to decision	118 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 ...
