

**K973794 S-57 VIDEO IMAGING SYSTEM**Jan 2, 1998  
88 days to decisionK973794 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k973794/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Oct 6, 1997
Decision date	Jan 2, 1998
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sopro</b>
Location	Marseille, FR
Contact	PIERRE MONTILLOT
Website	<a href="http://www.soprole.cl/">http://www.soprole.cl/</a>
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 ...

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