

**K013090 SOPRO 67D OPERATING ROOM CAMERA**Dec 13, 2001  
87 days to decisionK013090 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k013090/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received         | Sep 17, 2001                                 |
| Decision date         | Dec 13, 2001                                 |
| Days to decision      | 87 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Statement                                    |

**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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