FDA 510(k) Premarket Notification

K020270 SOPRO 367D 3CCD FULL DIGITAL ENDOSCOPY CAMERA

CLEARED

Mar 14, 2002
45 days to decision

K020270 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k020270/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jan 28, 2002
Decision date	Mar 14, 2002
Days to decision	45 days
Third-party review	No
Summary / Statement	Statement

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 ...