

K103813 SOPRO 281Mar 22, 2011
83 days to decisionK103813 · Product code: **NTN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k103813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Led Light Source (NTN)
Date received	Dec 29, 2010
Decision date	Mar 22, 2011
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sopro
Location	Marseille, FR
Contact	RICK ROSATI
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 ...
