FDA 510(k) Premarket Notification

K880171 MODEL 4900 ND:YAG LASER FOR GASTRO & GENITOUR APPL

CLEARED

Apr 11, 1988
87 days to decision

K880171 · Product code: **LNK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k880171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser For Gastro-urology Use (LNK)
Date received	Jan 15, 1988
Decision date	Apr 11, 1988
Days to decision	87 days
Third-party review	No

APPLICANT

Company	**Cooper Lasersonics, Inc.**
Location	Orangeburg, NY, US
Contact	CHARLES L ROSE
Website	https://www.cooperhealthcare.com
510(k) history	54 submissions · 52 cleared · 1982-1988

Cooper Lasersonics, Inc. is a medical device manufacturer based in Orangeburg, US, specializing in laser surgical systems. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1982. Cooper Lasersonics focused primarily on CO2 and Nd:YAG laser systems for surgical applications across multiple specialties, including general and plastic surgery, otolaryngology, gastroenterology, and neurosurgery. The company's regulatory activity concluded in 1988, making this a historical record of its contributions to surgical laser technology....

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Device record: https://www.510kdatabase.net/k880171/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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