FDA 510(k) Premarket Notification

K873790 MODELS 4000/6000/8000/8900 LASER FOR DERMA/SURGERY

CLEARED

Jan 22, 1988
126 days to decision

K873790 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k873790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 18, 1987
Decision date	Jan 22, 1988
Days to decision	126 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....