FDA 510(k) Premarket Notification

K844668 MODEL 8000 ND:YAG LASER SYS TREATMENT OF BENIGN LE

CLEARED

Jan 3, 1985
34 days to decision

K844668 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k844668/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Nov 30, 1984
Decision date	Jan 3, 1985
Days to decision	34 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....