FDA 510(k) Premarket Notification

K840145 MONITOR CO2 LASER SURGICAL SYSTEM

CLEARED

Apr 25, 1984
103 days to decision

K840145 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k840145/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Jan 13, 1984
Decision date	Apr 25, 1984
Days to decision	103 days
Third-party review	No

APPLICANT

Company	**Cooper Lasersonics, Inc.**
Location	Orangeburg, NY, US
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....