

K864983 CUSA SYSTEM 200 MACRO-DISSECTORJun 23, 1987
183 days to decisionK864983 · Product code: **LFL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k864983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Dec 22, 1986
Decision date	Jun 23, 1987
Days to decision	183 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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