

K827913 NIIC CO2 LASER SYSTEM MODEL 6OZ.Sep 13, 1982
31 days to decision

K827913 · Radiology

Source: <https://www.510kdatabase.net/k827913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Aug 13, 1982
Decision date	Sep 13, 1982
Days to decision	31 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....
