

**K828328 ULTRASCAN DIGITAL A/SYSTEM III**Mar 3, 1983  
78 days to decision

K828328 · Radiology

Source: <https://www.510kdatabase.net/k828328/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Dec 15, 1982
Decision date	Mar 3, 1983
Days to decision	78 days
Third-party review	No

**APPLICANT**

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Company	<b>Cooper Lasersonics, Inc.</b>
Location	Orangeburg, NY, US
Website	<a href="https://www.cooperhealthcare.com">https://www.cooperhealthcare.com</a>
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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