

**K842412 MODEL 4000 MD-YAG LASER FOR MALIGNANT**Jun 26, 1984  
7 days to decisionK842412 · Product code: **HQF** · Ophthalmic  
Source: <https://www.510kdatabase.net/k842412/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Laser, Ophthalmic (HQF)            |
| Date received         | Jun 19, 1984                       |
| Decision date         | Jun 26, 1984                       |
| Days to decision      | 7 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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