

**K883925 UROIMAGER**Dec 15, 1988  
90 days to decisionK883925 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k883925/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received         | Sep 16, 1988                                   |
| Decision date         | Dec 15, 1988                                   |
| Days to decision      | 90 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ausonics Pty , Ltd.</b>              |
| Location       | Mchenry, IL, US                         |
| Contact        | WILLIAM C NEALON                        |
| 510(k) history | 27 submissions · 26 cleared · 1979-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883925/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 20, 2026