

**K874211 EUB-450 DIAGNOSTIC ULTRASOUND DEVICE**Jun 23, 1988  
251 days to decisionK874211 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k874211/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received         | Oct 16, 1987                                   |
| Decision date         | Jun 23, 1988                                   |
| Days to decision      | 251 days                                       |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Hitachi Medical Corp. of America</b> |
| Location       | Tarrytown, NY, US                       |
| Contact        | UEHARA                                  |
| 510(k) history | 32 submissions · 31 cleared · 1985-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k874211/>, 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 21, 2026