

**K171824 Acclarix AX8 Diagnostic Ultrasound System, Acclarix LX8 Diagnostic Ultrasound System**Jul 18, 2017  
29 days to decisionK171824 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k171824/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received         | Jun 19, 2017                                   |
| Decision date         | Jul 18, 2017                                   |
| Days to decision      | 29 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Edan Instruments, Inc.</b>                                 |
| Location       | Shenzhen, CN  |
| Contact        | Alice Yang  |
| Website        | <a href="https://www.edan.com.cn">https://www.edan.com.cn</a> |
| 510(k) history | 92 submissions · 92 cleared · 2004-2026                       |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171824/> 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 16, 2026