

**K080970 USHIFU STEPPER**Jun 11, 2008  
68 days to decisionK080970 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k080970/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Transducer, Ultrasonic, Diagnostic (ITX) |
| Date received         | Apr 4, 2008                              |
| Decision date         | Jun 11, 2008                             |
| Days to decision      | 68 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|--|
| Company        | <b>Ushifu Development Company, LLC</b> |
| Location       | Deland, FL, US                         |
| Contact        | MARE RYAN                              |
| 510(k) history | 1 submissions · 1 cleared · 2008-2008  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080970/> 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 18, 2026