

**K192630 uWS-MI**Jun 11, 2020  
262 days to decisionK192630 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k192630/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Sep 23, 2019                                 |
| Decision date         | Jun 11, 2020                                 |
| Days to decision      | 262 days                                     |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shanghai United Imaging Healthcare Co., Ltd.</b>                         |
| Location       | Shanghai, CN  |
| Contact        | Xin Gao   |
| Website        | <a href="https://www.united-imaging.com">https://www.united-imaging.com</a> |
| 510(k) history | 82 submissions · 82 cleared · 2018-2026                                     |

Shanghai United Imaging Healthcare Co., Ltd. is a medical imaging company based in Shanghai, China. The company develops and manufactures advanced diagnostic imaging systems and related technologies. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. FDA 510(k) clearances span from 2018 to 2026, demonstrating sustained regulatory activity and recent market approvals. Recent cleared devices include advanced imaging systems such as magnetic resonance imaging (MRI) platforms, computed tomography (CT) scan...

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