

**K173953 uDR 780i**Jan 26, 2018  
30 days to decisionK173953 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k173953/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Stationary (KPR)    |
| Date received         | Dec 27, 2017                       |
| Decision date         | Jan 26, 2018                       |
| Days to decision      | 30 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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