

K183144 uMC 560iDec 19, 2019
401 days to decisionK183144 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k183144/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | Nov 13, 2018 |
| Decision date | Dec 19, 2019 |
| Days to decision | 401 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shanghai United Imaging Healthcare Co., Ltd. |
| Location | Shanghai, CN |
| Contact | Shumei Wang |
| Website | https://www.united-imaging.com |
| 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...
