

K210001 HYPER AIRApr 30, 2021
116 days to decisionK210001 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k210001/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received | Jan 4, 2021 |
| Decision date | Apr 30, 2021 |
| Days to decision | 116 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shanghai United Imaging Healthcare Co., Ltd. |
| Location | Shanghai, CN |
| Contact | Xin GAO |
| 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...