

K252992 CT Rembra RTMar 23, 2026
186 days to decisionK252992 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k252992/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Sep 18, 2025 |
| Decision date | Mar 23, 2026 |
| Days to decision | 186 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | CT Areta RT; CT Rembra |

APPLICANT

| | |
|----------------|--|
| Company | Philips Healthcare (Suzhou) Co., Ltd. |
| Location | Suzhou Jiangsu, CN |
| Contact | Tiffany Zhang |
| 510(k) history | 17 submissions · 17 cleared · 2014-2026 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Philips Medical Systems Technologies , Ltd. |
| Contact | Tiffany Zhang |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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