

K123576 IMR SOFTWARE APPLICATIONJun 7, 2013
199 days to decisionK123576 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k123576/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Nov 20, 2012 |
| Decision date | Jun 7, 2013 |
| Days to decision | 199 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Philips Healthcare (Cleveland) |
| Location | Cleveland, OH, US |
| Contact | CHRISTINE ANDERSON |
| 510(k) history | 6 submissions · 6 cleared · 2011-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123576/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026