

K172983 HealthCCSJun 13, 2018
259 days to decisionK172983 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k172983/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Sep 27, 2017 |
| Decision date | Jun 13, 2018 |
| Days to decision | 259 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Zebra Medical Vision, Ltd. |
| Location | Sefayim, IL |
| Contact | Matan Neeman |
| 510(k) history | 9 submissions · 9 cleared · 2018-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172983/> 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 26, 2026