

K161157 Vitrea CT Dual Energy Image ViewNov 3, 2016
192 days to decisionK161157 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k161157/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Apr 25, 2016 |
| Decision date | Nov 3, 2016 |
| Days to decision | 192 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Vital Images, Inc. |
| Location | St. Paul, MN, US |
| Contact | Alexis Erazo |
| 510(k) history | 41 submissions · 41 cleared · 1995-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161157/> 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 June 18, 2026