

K923585 DIGITAL FLUORO STOREOct 21, 1992
93 days to decisionK923585 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k923585/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Fluoroscopic, Image-intensified (JAA) |
| Date received | Jul 20, 1992 |
| Decision date | Oct 21, 1992 |
| Days to decision | 93 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Eigen |
| Location | Nevada City, CA, US |
| Contact | MARK A HOFFMAN |
| 510(k) history | 16 submissions · 16 cleared · 1988-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k923585/> 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