

K251520 Cios Alpha

Jul 9, 2025
54 days to decision

K251520 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k251520/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | May 16, 2025 |
| Decision date | Jul 9, 2025 |
| Days to decision | 54 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Cios Flow |

APPLICANT

| | |
|----------------|--|
| Company | Siemens Medical Solutions USA, Inc. |
| Location | Hoffman Estates, IL, US |
| Contact | Patricia Jones |
| 510(k) history | 778 submissions · 778 cleared · 1980-2026 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251520/> 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 13, 2026