

**K230221 QDOSE® Multi-purpose Voxel Dosimetry
(Personalized Dosimetry in Molecular Radiotherapy)**Aug 28, 2023
214 days to decisionK230221 · Product code: IYX · Radiology
Source: <https://www.510kdatabase.net/k230221/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Camera, Scintillation (gamma) (IYX) |
| Date received | Jan 26, 2023 |
| Decision date | Aug 28, 2023 |
| Days to decision | 214 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Versant Medical Physics and Radiation Safety |
| Location | Kalamazoo, MI, US |
| Contact | Darrell R. Fisher |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230221/>. 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