

K222662 Vitrea CT Cardiac AnalysisOct 14, 2022
42 days to decisionK222662 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k222662/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Sep 2, 2022 |
| Decision date | Oct 14, 2022 |
| Days to decision | 42 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Canon Medical Informatics, Inc. |
| Location | Minnetonka, MN, US |
| Contact | Jay Vaishnav |
| 510(k) history | 4 submissions · 4 cleared · 2022-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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