

**K210209 Viz ICH**Mar 23, 2021  
56 days to decisionK210209 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k210209/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Radiological Computer-assisted Triage And Notification Software (QAS) |
| Date received         | Jan 26, 2021  |
| Decision date         | Mar 23, 2021  |
| Days to decision      | 56 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Viz. Ai, Inc.</b>                    |
| Location       | Palo Alto, CA, US                       |
| Contact        | Gregory Ramina                          |
| 510(k) history | 11 submissions · 10 cleared · 2018-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210209/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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