FDA 510(k) Premarket Notification

# K193658 Viz ICH

K193658 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k193658/

**CLEARED**

Mar 18, 2020
79 days to decision

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radiological Computer-assisted Triage And Notification Software (QAS) |
| Date received | Dec 30, 2019 |
| Decision date | Mar 18, 2020 |
| Days to decision | 79 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k193658/ 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