FDA 510(k) Premarket Notification

# K222884 Rapid NCCT Stroke

**CLEARED**

Mar 2, 2023
161 days to decision

K222884 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k222884/

## 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 | Sep 22, 2022 |
| Decision date | Mar 2, 2023 |
| Days to decision | 161 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Ischemaview, Inc.** |
| Location | Irvine, CA, US |
| Contact | James Rosa |
| 510(k) history | 21 submissions · 21 cleared · 2013-2025 |