FDA 510(k) Premarket Notification

# K210791 Us2.v1

**CLEARED**

Jul 27, 2021
133 days to decision

K210791 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k210791/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | Mar 16, 2021 |
| Decision date | Jul 27, 2021 |
| Days to decision | 133 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Eko.Ai Pte Ltd. D/B/A Us2.Ai** |
| Location | Singapore, SG |
| Contact | James Hare |
| 510(k) history | 3 submissions · 3 cleared · 2021-2025 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Enzyme Corporation** |
| Contact | Jared Seehafer |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210791/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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