FDA 510(k) Premarket Notification

# K223347 UltraSight AI Guidance

**CLEARED**

Jul 24, 2023
265 days to decision

K223347 · Product code: **QJU** · Radiology
Source: https://www.510kdatabase.net/k223347/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Image Acquisition And/or Optimization Guided By Artificial Intelligence (QJU) |
| Date received | Nov 1, 2022 |
| Decision date | Jul 24, 2023 |
| Days to decision | 265 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Ultrasight, Inc.** |
| Location | Rehovot, IL |
| Contact | Davidi Vortman |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Hogan Lovells US LLP** |
| Contact | Janice M. Hogan |

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