

K212012 Follicle ClarityJan 19, 2022
205 days to decisionK212012 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k212012/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | Jun 28, 2021 |
| Decision date | Jan 19, 2022 |
| Days to decision | 205 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cycle Clarity |
| Location | Awendaw, SC, US |
| Contact | John Schnorr |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

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