

K203244 CellChek 20 rcJun 15, 2021
224 days to decisionK203244 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k203244/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Management, Ophthalmic (NFJ) |
| Date received | Nov 3, 2020 |
| Decision date | Jun 15, 2021 |
| Days to decision | 224 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Konan Medical, Inc. |
| Location | Hyogo, JP |
| Contact | Runa Emura |
| 510(k) history | 7 submissions · 7 cleared · 1995-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Matrix Medical Consulting, Inc. |
| Contact | Alan Donald |

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

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