

K203688 Clear AlignerOct 8, 2021
295 days to decisionK203688 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k203688/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Aligner, Sequential (NXC) |
| Date received | Dec 17, 2020 |
| Decision date | Oct 8, 2021 |
| Days to decision | 295 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Wuxi EA Medical Instruments Technologies Limited. |
| Location | Wuxi, CN |
| Contact | Yan He |
| 510(k) history | 2 submissions · 2 cleared · 2021-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Shanghai Sungo Management Consulting Company Limited. |
| Contact | Ivy Wang |

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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