

K231884 TRIOCLEAR SystemSep 1, 2023
66 days to decisionK231884 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k231884/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Aligner, Sequential (NXC) |
| Date received | Jun 27, 2023 |
| Decision date | Sep 1, 2023 |
| Days to decision | 66 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Modern Dental Laboratory (Dg) Co., Ltd. |
| Location | Dongguan, CN |
| Contact | Robin Liu |
| 510(k) history | 2 submissions · 2 cleared · 2023-2024 |

REGULATORY CONSULTANT

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|-----------------|---|
| Consulting firm | Modern Dental Laboratory Co., Ltd. |
| Contact | Robin Liu |

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

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