

**K221475 MyClearALIGN Dental Aligner System**Aug 31, 2022  
103 days to decisionK221475 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k221475/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Aligner, Sequential (NXC)          |
| Date received         | May 20, 2022                       |
| Decision date         | Aug 31, 2022                       |
| Days to decision      | 103 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Key Dental Technologies, LLC</b>   |
| Location       | Chapel Hill, NC, US                   |
| Contact        | Larry Moray                           |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------------|
| Consulting firm | <b>Schiff &amp; Company, Inc.</b> |
| Contact         | Thomas Padula                     |

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221475/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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