

**K212803 DailyMate Orthodontic Aligner System**May 23, 2022  
263 days to decisionK212803 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k212803/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Aligner, Sequential (NXC)          |
| Date received         | Sep 2, 2021                        |
| Decision date         | May 23, 2022                       |
| Days to decision      | 263 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>3D Global Biotech, Inc.</b>        |
| Location       | New Taipei City 221, TW               |
| Contact        | Keng-Liang Ou                         |
| 510(k) history | 2 submissions · 2 cleared · 2019-2022 |

**REGULATORY CONSULTANT**

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|-----------------|---------------------|
| Consulting firm | <b>Duocare, LLC</b> |
| Contact         | Diana Lam           |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212803/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026