

**K212125 Nobel Biocare Dental Implant Systems Portfolio - MR  
Conditional**Sep 24, 2021  
79 days to decisionK212125 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k212125/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Jul 7, 2021                          |
| Decision date         | Sep 24, 2021                         |
| Days to decision      | 79 days                              |
| Third-party review    | No                                   |
| Combination product   | No                                   |
| PCCP authorized       | No                                   |
| Summary / Statement   | Statement                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Nobel Biocare AG</b>               |
| Location       | Kloten, CH                            |
| Contact        | Bernice Jim                           |
| 510(k) history | 2 submissions · 2 cleared · 2020-2021 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212125/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026