

**K210610 PrimeTaper EV Dental Implant**Aug 27, 2021  
179 days to decisionK210610 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k210610/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Mar 1, 2021                          |
| Decision date         | Aug 27, 2021                         |
| Days to decision      | 179 days                             |
| Third-party review    | No                                   |
| Combination product   | No                                   |
| PCCP authorized       | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dentsply Sirona, Inc.</b>                                  |
| Location       | York, PA, US  |
| Contact        | Karl J Nittinger  |
| Website        | <a href="http://www.dentsply.com">http://www.dentsply.com</a> |
| 510(k) history | 21 submissions · 21 cleared · 2019-2026                       |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210610/> 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 13, 2026