

**K170384 Dentium NR Line CAD/CAM Abutments**Aug 17, 2017  
191 days to decisionK170384 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k170384/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Abbreviated                                 |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received         | Feb 7, 2017                                 |
| Decision date         | Aug 17, 2017                                |
| Days to decision      | 191 days                                    |
| Third-party review    | No  |
| Summary / Statement   | Statement                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dentium Co., Ltd.</b>                |
| Location       | Dunwoody, GA, US                        |
| Contact        | Sangpil Yoon                            |
| 510(k) history | 22 submissions · 22 cleared · 2004-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170384/> 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 27, 2026