

**K150344 Dentis Dental Implant System**Jul 24, 2015  
163 days to decisionK150344 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k150344/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Feb 11, 2015                         |
| Decision date         | Jul 24, 2015                         |
| Days to decision      | 163 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dentis Co., Ltd.</b>   |
| Location       | Dalseo-Gu, KR   |
| Contact        | JINJU LEE   |
| Website        | <a href="https://www.dentis.co.kr">https://www.dentis.co.kr</a> |
| 510(k) history | 37 submissions · 37 cleared · 2008-2026                         |

Dentis Co., Ltd. is a Dental device manufacturer based in Dalseo-Gu, South Korea. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Dental devices, with a regulatory history spanning from 2008 to 2026. The company remains active, with recent clearances demonstrating ongoing product development and market engagement. Dentis specializes in dental implant systems, abutments, and associated clinical equipment. Recent cleared devices include implant fixtures, abutment components, scanning and healing systems, and dental chairs, ref...

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