

**K252197 Nobel Biocare S Series Implants**Feb 18, 2026  
219 days to decisionK252197 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k252197/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Jul 14, 2025                         |
| Decision date         | Feb 18, 2026                         |
| Days to decision      | 219 days                             |
| Third-party review    | No                                   |
| Combination product   | No                                   |
| PCCP authorized       | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nobel Biocare AB</b>   |
| Location       | Goteborg, SE  |
| Contact        | Bernice Jim   |
| Website        | <a href="https://www.nobelbiocare.com">https://www.nobelbiocare.com</a> |
| 510(k) history | 92 submissions · 92 cleared · 2002-2026                                 |

Nobel Biocare AB is a medical device manufacturer based in Goteborg, Sweden. The company specializes in implant systems and related technologies for oral and maxillofacial applications. Nobel Biocare AB has received FDA 510(k) clearances from total submissions since 2002. The company's regulatory portfolio is dominated by Dental devices, which account for approximately 86% of submissions. Recent clearances include implant systems, abutments, and digital imaging software, with the latest FDA 510(k) clearance in 2026, demonstrating continued regulatory activity. The company...