

K133731 NOBELACTIVE WIDE PLATFORM (WP)May 8, 2014
153 days to decisionK133731 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k133731/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Dec 6, 2013 |
| Decision date | May 8, 2014 |
| Days to decision | 153 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nobel Biocare AB |
| Location | Goteborg, SE |
| Contact | PHUONG NGUYEN |
| Website | https://www.nobelbiocare.com |
| 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...
