

**K072980 NOBELPERFECT CONICAL CONNECTION
HEXAGONAL IMPLANTS**Dec 20, 2007
58 days to decisionK072980 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k072980/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Oct 23, 2007 |
| Decision date | Dec 20, 2007 |
| Days to decision | 58 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------------------------------------|
| Company | Nobel Biocare AB |
| Location | Goteborg, SE |
| Contact | KAM LEUNG |
| 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...