

K091907 NOBELPROCERA IMPLANT BRIDGE ZIRCONIAOct 6, 2009
103 days to decisionK091907 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k091907/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Jun 25, 2009 |
| Decision date | Oct 6, 2009 |
| Days to decision | 103 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nobel Biocare AB |
| Location | Goteborg, SE |
| Contact | HERBERT CRANE |
| 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...
