

**K243834 NobelZygoma TiUltra Implant system**Aug 25, 2025  
255 days to decisionK243834 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k243834/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 13, 2024
Decision date	Aug 25, 2025
Days to decision	255 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	Jim Bernice
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...