

**K152836 TREFOIL System**Apr 11, 2016  
195 days to decisionK152836 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k152836/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 29, 2015
Decision date	Apr 11, 2016
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nobel Biocare AB</b>
Location	Goteborg, SE
Contact	CHARLEMAGNE CHUA
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...

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