

K170135 TREFOIL SystemMay 11, 2017
114 days to decisionK170135 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k170135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 17, 2017
Decision date	May 11, 2017
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nobel Biocare AB
Location	Goteborg, SE
Contact	Charlemagne Chua
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...

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