FDA 510(k) Premarket Notification

K173418 NobelParallel Conical Connection

CLEARED

Feb 21, 2019
477 days to decision

K173418 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k173418/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 1, 2017
Decision date	Feb 21, 2019
Days to decision	477 days
Third-party review	No
Combination product	No
PCCP authorized	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...

REGULATORY CONSULTANT

Consulting firm	**Nobel Biocare USA, LLC**
Contact	Charlemagne Chua

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov