

K181932 DTX Studio design

Mar 1, 2019
225 days to decision

K181932 · Product code: **PNP** · Dental
Source: <https://www.510kdatabase.net/k181932/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Abutment Design Software For Dental Laboratory (PNP)
Date received	Jul 19, 2018
Decision date	Mar 1, 2019
Days to decision	225 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](https://accessdata.fda.gov)
