

K191475 Nobel Biocare N1 PureSet Tray, Nobel Biocare N1 PureSet Plate, Prosthetic PureSet Tray, Prosthetic PureSet PlateAug 29, 2019
86 days to decisionK191475 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k191475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Jun 4, 2019
Decision date	Aug 29, 2019
Days to decision	86 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 Services AG
Contact	Elena Cavallini

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191475/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026