

K161634 IPS CaseDesignerNov 10, 2016
149 days to decisionK161634 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k161634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 14, 2016
Decision date	Nov 10, 2016
Days to decision	149 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...
