

**K231898 DTX Studio Clinic (4.0)**Dec 8, 2023  
163 days to decisionK231898 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k231898/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 28, 2023
Decision date	Dec 8, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nobel Biocare AB</b>
Location	Goteborg, SE
Contact	Mieke Roelants
Website	<a href="https://www.nobelbiocare.com">https://www.nobelbiocare.com</a>
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**

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Consulting firm	<b>Nobel Biocare C/O Medicim NV</b>
Contact	Mieke Roelants

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

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