FDA 510(k) Premarket Notification

K221921 DTX Studio Clinic 3.0

CLEARED

Mar 28, 2023
270 days to decision

K221921 · Product code: **MYN** · Radiology
Source: https://www.510kdatabase.net/k221921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Jul 1, 2022
Decision date	Mar 28, 2023
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nobel Biocare AB**
Location	Goteborg, SE
Contact	Wim Vrydag
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 C/O Medicim NV**
Contact	Wim Vrydag

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