

K252086 DTX Studio AssistNov 17, 2025
138 days to decisionK252086 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k252086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Jul 2, 2025
Decision date	Nov 17, 2025
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nobel Biocare C/O Medicim NV
Location	Mechelen, BE
Contact	Mieke Roelants
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252086/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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