

**K242637 MEM Clear Aligner System**May 21, 2025  
260 days to decisionK242637 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k242637/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 3, 2024
Decision date	May 21, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mem Dental Technology Co., Ltd.</b>
Location	Tainan City, TW
Contact	Maggie Wei
510(k) history	2 submissions · 2 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Leadtheway International Corp.</b>
Contact	Roger Chen

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242637/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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