

**K232889 METICULY Patient-specific titanium maxillofacial mesh implant**Apr 30, 2024  
225 days to decisionK232889 · Product code: JEY · Dental  
Source: <https://www.510kdatabase.net/k232889/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Sep 18, 2023
Decision date	Apr 30, 2024
Days to decision	225 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Meticuly Co., Ltd.</b>
Location	Muang Nonthaburi, TH
Contact	Peeranoot Lohwongwatana
510(k) history	3 submissions · 3 cleared · 2021-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdr Solutions Co., Ltd.</b>
Contact	Paweena U-Thainual

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232889/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026