

**K212561 MTX-C1**Sep 27, 2022  
410 days to decisionK212561 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212561/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 13, 2021
Decision date	Sep 27, 2022
Days to decision	410 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ilooda Co.,, Ltd.</b>
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	Yun-Jung Ha
510(k) history	16 submissions · 16 cleared · 2015-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtechgroup</b>
Contact	Dave Kim

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

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