

## 510(k) Premarket Notification



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<b>Device Classification Name</b>	<a href="#">Electrosurgical, Cutting &amp; Coagulation &amp; Accessories</a> <sup>22</sup>
<b>510(k) Number</b>	K212561
<b>Device Name</b>	MTX-C1
<b>Applicant</b>	ILOODA Co., Ltd 120, Jangan-Ro 458 Beon-Gil, Jangan-Gu Suwon-Si, KR 16200
<b>Applicant Contact Correspondent</b>	Yun-Jung Ha Mtech Group 7505 Fannin St. Ste 610 Houston, TX 77054
<b>Correspondent Contact</b>	Dave Kim
<b>Regulation Number</b>	<a href="#">878.4400</a> <sup>23</sup>
<b>Classification Product Code</b>	<a href="#">GEI</a> <sup>24</sup>
<b>Date Received</b>	08/13/2021
<b>Decision Date</b>	09/27/2022
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	General & Plastic Surgery
<b>510k Review Panel</b>	General & Plastic Surgery
<b>Summary</b>	<a href="#">Summary</a> <sup>25</sup>
<b>Type</b>	Traditional
<b>Reviewed by Third Party</b>	No
<b>Combination Product</b>	No

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Page Last Updated: 12/09/2024

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