510(k) Premarket Notification

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

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