

K232241 Disposable Microwave Ablation Needle (T-1408, T-1410, T-1608, T-1610, L-1815, L-1818, L-2015, L-2018)Nov 13, 2023
108 days to decisionK232241 · Product code: **NEY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k232241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Jul 28, 2023
Decision date	Nov 13, 2023
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Betters(Suzhou) Medical Co., Ltd.
Location	Suzhou, CN
Contact	Lei Liu
510(k) history	2 submissions · 2 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	APlus Healthcare Technology (Shanghai) Co., Ltd.
Contact	Ada Wang

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

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