

K253771 Disposable Microwave Ablation Antenna (DW-XR-II1, DW-XR-II3, DW-XR-II4, DW-XR-II14, DW-XR-II5, DW-XR-II6, DW-XR-II7, DW-XR-II8, DW-XR-II9, DW-XR-II10, DW-XR-II18, DW-XR-II19, DW-XR-II20, DW-XR-II21, DW-DG-II6, DW-DG-II7, DW-DG-II9, DW-DG-II10, DW-DG-II13)

Mar 2, 2026
96 days to decision

K253771 · Product code: **NEY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253771/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Nov 26, 2025
Decision date	Mar 2, 2026
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanjing Devin Medical Technology Co., Ltd.
Location	Nanjing, CN
Contact	Qiuling Liu
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	APlus Healthcare Technology (Shanghai) Co., Ltd.
Contact	Jack Fang

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