

K233140 Microwave Ablation Device (Exceed S10U)Jan 31, 2024
126 days to decisionK233140 · Product code: **NEY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Sep 27, 2023
Decision date	Jan 31, 2024
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sterile Microwave Ablation Probe (Exact)

APPLICANT

Company	Hygea Medical Technology Co., Ltd.
Location	Beijing, CN
Contact	Jinping Duan
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233140/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026