

K230767 Pelvic Floor Muscle StimulatorSep 21, 2023
185 days to decisionK230767 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Mar 20, 2023
Decision date	Sep 21, 2023
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanjing Vishee Medical Technology Co., Ltd.
Location	Nanjing, CN
Contact	Qiu Kai
510(k) history	2 submissions · 2 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230767/> 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 26, 2026