

K210441 Incontinence ProbeSep 17, 2021
217 days to decisionK210441 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Feb 12, 2021
Decision date	Sep 17, 2021
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Med-Link Electronics Tech Co., Ltd.
Location	Nederland, CO, US
Contact	Yongfen Yang
510(k) history	14 submissions · 14 cleared · 2009-2026

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