

**K220161 Biofeedback Nerve and Muscle Stimulator**Jul 20, 2022  
181 days to decisionK220161 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k220161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jan 20, 2022
Decision date	Jul 20, 2022
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Konmed Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	ShuiShan Yin
510(k) history	6 submissions · 6 cleared · 2018-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangzhou GLOMED Biological Technology Co., Ltd.</b>
Contact	Cassie Lee

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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