FDA 510(k) Premarket Notification

CLEARED

K220161 Biofeedback Nerve and Muscle Stimulator

Jul 20, 2022
181 days to decision

K220161 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k220161/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Guangzhou GLOMED Biological Technology Co., Ltd.**
Contact	Cassie Lee

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