FDA 510(k) Premarket Notification

CLEARED

K233576 Konmed Incontinence Stimulation Electrode (Vaginal Probe: KM-503, KM-504, KM-505, KM-506, KM-507, KM-5013

Feb 23, 2024
108 days to decision

K233576 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233576/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Nov 7, 2023
Decision date	Feb 23, 2024
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Rectal Probe: KM-502, KM-5018)

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 Technoloy Co., Ltd.**
Contact	Cassie Lee

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