FDA 510(k) Premarket Notification

K230983 Unicare (K-UNICARE-USA)

CLEARED

Oct 20, 2023
197 days to decision

K230983 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Apr 6, 2023
Decision date	Oct 20, 2023
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tenscare, Ltd.**
Location	Timperley, Cheshire, GB
Contact	Saskia Eldridge-Hinmers
510(k) history	13 submissions · 13 cleared · 2001-2024