

K230780 MFG-05Oct 5, 2023
197 days to decisionK230780 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k230780/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Mar 22, 2023
Decision date	Oct 5, 2023
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer Medizinsysteme GmbH
Location	Neu-Ulm, DE
Contact	Ute Killet
510(k) history	13 submissions · 13 cleared · 2016-2026

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