

**K230983 Unicare (K-UNICARE-USA)**Oct 20, 2023  
197 days to decisionK230983 · Product code: **KPI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k230983/>**SUBMISSION DETAILS**

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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**

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Company	<b>Tenscare, Ltd.</b>
Location	Timperley, Cheshire, GB
Contact	Saskia Eldridge-Hinners
510(k) history	13 submissions · 13 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230983/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026