

**K191312 Perfect PFE**Nov 1, 2019  
170 days to decisionK191312 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k191312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	May 15, 2019
Decision date	Nov 1, 2019
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tenscare, Ltd.</b>
Location	Timperley, Cheshire, GB
Contact	Andrew Brown
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/k191312/> 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 25, 2026