

**K231780 Perifit Care+**Dec 20, 2023  
187 days to decisionK231780 · Product code: **HIR** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k231780/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Jun 16, 2023
Decision date	Dec 20, 2023
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X6 Innovations</b>
Location	Paris, FR
Contact	Robin Reynaud
510(k) history	3 submissions · 3 cleared · 2023-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Lina Kontos

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231780/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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