FDA 510(k) Premarket Notification

K231780 Perifit Care+

CLEARED

Dec 20, 2023
187 days to decision

K231780 · Product code: **HIR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k231780/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Lina Kontos

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