FDA 510(k) Premarket Notification

K231785 Perifit Pump

CLEARED

Jan 26, 2024
220 days to decision

K231785 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k231785/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 20, 2023
Decision date	Jan 26, 2024
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**X6 Innovations**
Location	Paris, FR
Contact	Artem Rodionov
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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k231785/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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