FDA 510(k) Premarket Notification

K232047 VIVACE

CLEARED

Mar 28, 2024
262 days to decision

K232047 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k232047/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jul 10, 2023
Decision date	Mar 28, 2024
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Unimom.Co**
Location	Osan-Si, KR
Contact	Chon Yeong-Bin
510(k) history	4 submissions · 4 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	**Global Medical Standard Consulting Co., Ltd.**
Contact	Jong-Hyun Kim

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