FDA 510(k) Premarket Notification

K222573 imani i2Plus Breast Pump

CLEARED

Mar 3, 2023
190 days to decision

K222573 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k222573/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Aug 25, 2022
Decision date	Mar 3, 2023
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Imani Co.**
Location	Yongin-Si, KR
Contact	Hyo-Soon Hwang
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Global Medical Standard Consulting Co., Ltd.**
Contact	Kyung Jin Lee

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