FDA 510(k) Premarket Notification

K202045 imani i1

CLEARED

Feb 26, 2021
218 days to decision

K202045 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k202045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jul 23, 2020
Decision date	Feb 26, 2021
Days to decision	218 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	Do Gyun Lim

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