

K202045 imani i1Feb 26, 2021
218 days to decisionK202045 · Product code: **HGX** · Obstetrics & GynecologySource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026