

**K202037 imani i2**Mar 1, 2021  
221 days to decisionK202037 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k202037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jul 23, 2020
Decision date	Mar 1, 2021
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Global Medical Standard Consulting Co., Ltd.</b>
Contact	Do Gyun Lim

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202037/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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