

K211016 Powered Breast Pump (Models 7V and 7X)Jun 29, 2022
450 days to decisionK211016 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k211016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Apr 5, 2021
Decision date	Jun 29, 2022
Days to decision	450 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Haenim Co., Ltd.
Location	Incheon, KR
Contact	Dae Won Kim
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211016/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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