

K221708 CIMILRE Free-T2 PlusDec 23, 2022
193 days to decisionK221708 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k221708/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 13, 2022
Decision date	Dec 23, 2022
Days to decision	193 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cimilre Co., Ltd.
Location	Seongnam-Si, KR
Contact	Not Provided
510(k) history	2 submissions · 2 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	DAVE YUNGVIRT

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

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