

**K191110 HeraBEAT™ US**Nov 14, 2019  
202 days to decisionK191110 · Product code: **KNG** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k191110/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Apr 26, 2019
Decision date	Nov 14, 2019
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heramed, Ltd.</b>
Location	Netanya, IL
Contact	Dganit Litinsky
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Solutions, LLC</b>
Contact	Sheila Hemeon-Heyer

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/k191110/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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