

**K250897 Koala Intrauterine Pressure Catheter (IPC-5000E)**May 22, 2025  
58 days to decisionK250897 · Product code: **HFN** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Intrauterine (HFN)
Date received	Mar 25, 2025
Decision date	May 22, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clinical Innovations, LLC</b>
Location	Murray, UT, US
Contact	Alex Garrett
510(k) history	9 submissions · 9 cleared · 2007-2025

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