

**K210628 X-FLO Fluid Management System**Nov 4, 2021  
247 days to decisionK210628 · Product code: **HIG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k210628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Hysteroscopic (HIG)
Date received	Mar 2, 2021
Decision date	Nov 4, 2021
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Thermedx, LLC</b>
Location	Solon, OH, US
Contact	Daniel Marijian
510(k) history	5 submissions · 5 cleared · 2010-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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