

K172048 FluidSmartSep 5, 2017
61 days to decisionK172048 · Product code: **HIG** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k172048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Insufflator, Hysteroscopic (HIG)
Date received	Jul 6, 2017
Decision date	Sep 5, 2017
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermedx, LLC
Location	Solon, OH, US
Contact	Homer Gregory
510(k) history	5 submissions · 5 cleared · 2010-2021

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