

K133799 THERMEDX FLUID MANAGMENT SYSTEMJun 20, 2014
189 days to decisionK133799 · Product code: **HIG** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k133799/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Hysteroscopic (HIG)
Date received	Dec 13, 2013
Decision date	Jun 20, 2014
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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