

K180096 GDT-1000 SystemApr 16, 2018
90 days to decisionK180096 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k180096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jan 16, 2018
Decision date	Apr 16, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acuvu, Inc.
Location	Redwood City, CA, US
Contact	Sam Mostafavi
510(k) history	2 submissions · 2 cleared · 2018-2021

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