

K211227 HTx Disposable Hysteroscope SystemSep 15, 2021
145 days to decisionK211227 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k211227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Apr 23, 2021
Decision date	Sep 15, 2021
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	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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