

K223520 UNIDRIVE SIII SystemApr 27, 2023
155 days to decisionK223520 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k223520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Nov 23, 2022
Decision date	Apr 27, 2023
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	Alita McElroy
510(k) history	361 submissions · 361 cleared · 1980-2024

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