

K071754 NEO-VAGINA SURGERY SET AND ACCESSORIESJan 7, 2009
559 days to decisionK071754 · Product code: **HDX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k071754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	Jun 28, 2007
Decision date	Jan 7, 2009
Days to decision	559 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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