

K160341 Colposcope SystemSep 14, 2016
219 days to decisionK160341 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k160341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Feb 8, 2016
Decision date	Sep 14, 2016
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xuzhou Kernel Medical Equipment Co., Ltd.
Location	Shanghai, CN
Contact	JING WANG
510(k) history	8 submissions · 8 cleared · 2014-2025

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