

K151878 Video ColposcopeDec 1, 2015
145 days to decisionK151878 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k151878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Jul 9, 2015
Decision date	Dec 1, 2015
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edan Instruments, Inc.
Location	Shenzhen, CN
Contact	Queena Chen
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151878/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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