

K132423 THE GYNOCULARApr 8, 2014
246 days to decisionK132423 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k132423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Aug 5, 2013
Decision date	Apr 8, 2014
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gynius AB
Location	Stockholm, SE
Contact	MATTHEW VOLSKY
510(k) history	1 submissions · 1 cleared · 2014-2014

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