

**K161065 ColpoWave™ Colpotomizer and CerviGrip™ Uterine Manipulator**Oct 27, 2016  
195 days to decisionK161065 · Product code: **HEW** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k161065/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culdoscope (and Accessories) (HEW)
Date received	Apr 15, 2016
Decision date	Oct 27, 2016
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Surgitools Pty , Ltd.</b>
Location	Woodvale, AU
Contact	Jai Singh
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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