

K051160 MANIPUSEALSep 2, 2005
120 days to decisionK051160 · Product code: **HEW** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k051160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culdoscope (and Accessories) (HEW)
Date received	May 5, 2005
Decision date	Sep 2, 2005
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Insitu Systems
Location	North Attleboro, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	1 submissions · 1 cleared · 2005-2005

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