

K160380 LT-300 HDMay 13, 2016
93 days to decisionK160380 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k160380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Feb 10, 2016
Decision date	May 13, 2016
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lutech Industries, Inc.
Location	Ronkonkoma, NY, US
Contact	Ronald Vachula
510(k) history	4 submissions · 4 cleared · 2014-2017

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