

K143119 LT-300 Video ColposcopeDec 18, 2014
49 days to decisionK143119 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k143119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Oct 30, 2014
Decision date	Dec 18, 2014
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143119/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026