

K190797 Reedgyn disposable hysteroscope (Model RH-2S-01 and Model RH-2D-01)Nov 18, 2019
235 days to decisionK190797 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Mar 28, 2019
Decision date	Nov 18, 2019
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reed Medical (Zhejiang) Co., Ltd.
Location	Pinghu, CN
Contact	Lu Zhong Zhong
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Shanghai Qisheng Business Consulting Co., Ltd.
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190797/>; 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 28, 2026