

K181545 Hysteroscope SystemMay 10, 2019
332 days to decisionK181545 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jun 12, 2018
Decision date	May 10, 2019
Days to decision	332 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai AnQing Medical Instrument Co., Ltd.
Location	Shanghai, CN
Contact	Lina FEI
Website	http://www.anqingmedical.com
510(k) history	14 submissions · 14 cleared · 2018-2026

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