

K210116 Video Endoscopy System, 3D Video Endoscopy SystemOct 13, 2021
267 days to decisionK210116 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k210116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Jan 19, 2021
Decision date	Oct 13, 2021
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Location	Cixi, CN
Contact	Ma Guofang
510(k) history	7 submissions · 7 cleared · 2019-2024

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