

K200216 4K UHD Camera SystemAug 21, 2020
206 days to decisionK200216 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k200216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Jan 28, 2020
Decision date	Aug 21, 2020
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scivita Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Ruqin Wu
510(k) history	12 submissions · 12 cleared · 2019-2026

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