

K193339 GTK Veress NeedlesJan 30, 2020
59 days to decisionK193339 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k193339/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Dec 2, 2019
Decision date	Jan 30, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou T.K Medical Instrument Co., Ltd.
Location	Guangzhou, CN
Contact	Tracy Weng
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Christy Young

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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