FDA 510(k) Premarket Notification

# K193339 GTK Veress Needles

**CLEARED**

Jan 30, 2020
59 days to decision

K193339 · Product code: **HIF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k193339/

## SUBMISSION DETAILS

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|---|---|
| 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