

K183675 3D Visualization SystemSep 25, 2019
271 days to decisionK183675 · Product code: **GCJ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k183675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 28, 2018
Decision date	Sep 25, 2019
Days to decision	271 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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