

K202688 AFS Medical Sterile Single-Use Access Port SystemOct 14, 2021
394 days to decisionK202688 · Product code: **OTJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscopic Single Port Access Device (OTJ)
Date received	Sep 15, 2020
Decision date	Oct 14, 2021
Days to decision	394 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Afs Medical Co. , Ltd.
Location	Gyeonggi-Do, KR
Contact	Min Ah Kim
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Lakeshore Medical Device Consulting, LLC
Contact	Michele Lucey

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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