

K212786 LevaLap Laparoscopic Access DeviceFeb 23, 2022
175 days to decisionK212786 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Sep 1, 2021
Decision date	Feb 23, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Core Access Surgical Technologies, Inc.
Location	Atlanta, GA, US
Contact	Marianne D. Jacklyn
510(k) history	1 submissions · 1 cleared · 2022-2022

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