

K211148 CORE-TrocarJun 21, 2022
428 days to decisionK211148 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Apr 19, 2021
Decision date	Jun 21, 2022
Days to decision	428 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Incore Co., Ltd.
Location	Daegu, KR
Contact	Jae-Hun Lee
510(k) history	6 submissions · 6 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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