

K220081 CORE-SPORTSep 28, 2022
261 days to decisionK220081 · Product code: **OTJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220081/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscopic Single Port Access Device (OTJ) |
| Date received | Jan 10, 2022 |
| Decision date | Sep 28, 2022 |
| Days to decision | 261 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220081/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026