

K243968 Revolve Surgical SystemOct 3, 2025
284 days to decisionK243968 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243968/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | Dec 23, 2024 |
| Decision date | Oct 3, 2025 |
| Days to decision | 284 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Revolve Surgical, Inc. |
| Location | Toronto, CA |
| Contact | Alex Gordon |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243968/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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