

**K240334 LAGIS Endoscopic Instruments - Grasper
(DI-5670-33D, DI-5670-45D, DI-5716-33D, DI-5716-45D,
DI-5719-33D, DI-5731-33D, DI-5731-45D, DI-5901-33D,
DI-5901-45D)**Oct 30, 2024
268 days to decisionK240334 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240334/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | Feb 5, 2024 |
| Decision date | Oct 30, 2024 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Lagis Enterprise Co., Ltd. |
| Location | Taichung City, TW |
| Contact | Lynn Chen |
| 510(k) history | 2 submissions · 2 cleared · 2024-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240334/> 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 14, 2026