

K242857 ClearHemograsperMay 21, 2025
243 days to decisionK242857 · Product code: **KGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k242857/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Forceps, Biopsy, Electric (KGE) |
| Date received | Sep 20, 2024 |
| Decision date | May 21, 2025 |
| Days to decision | 243 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Finemedix Co., Ltd. |
| Location | Daegu, KR |
| Contact | Youn Jung Choi |
| 510(k) history | 11 submissions · 11 cleared · 2018-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------|
| Consulting firm | KMC, Inc. |
| Contact | Woo Seok Jeong |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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