FDA 510(k) Premarket Notification

K242857 ClearHemograsper

CLEARED

May 21, 2025
243 days to decision

K242857 · Product code: **KGE** · Gastroenterology & Urology
Source: 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