FDA 510(k) Premarket Notification

K231267 ClearTip

CLEARED

Jun 30, 2023
59 days to decision

K231267 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k231267/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	May 2, 2023
Decision date	Jun 30, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Finemedix Co., Ltd.**
Location	Daegu, KR
Contact	Seok-Jun Ma
510(k) history	11 submissions · 11 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

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