FDA 510(k) Premarket Notification

K213239 Endoscopic Injection Needle

CLEARED

Jun 2, 2022
245 days to decision

K213239 · Product code: **FBK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Sep 30, 2021
Decision date	Jun 2, 2022
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Zksk Technology Co., Ltd.**
Location	Beijing, CN
Contact	Ma Li
510(k) history	6 submissions · 6 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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