FDA 510(k) Premarket Notification

K210017 ACTOnco, ACTOnco IVD

CLEARED

Dec 23, 2022
718 days to decision

K210017 · Product code: **PZM** · Pathology
Source: https://www.510kdatabase.net/k210017/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Next Generation Sequencing Based Tumor Profiling Test (PZM)
Date received	Jan 4, 2021
Decision date	Dec 23, 2022
Days to decision	718 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Act Genomics**
Location	Taipei, TW
Contact	Pei-Fang Chung
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**K2 Regulatory Consulting, LLC**
Contact	David Kern

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