FDA 510(k) Premarket Notification

K253905 PrimeSight UltraView System

CLEARED

Apr 7, 2026
123 days to decision

K253905 · Product code: **FAJ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k253905/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Dec 5, 2025
Decision date	Apr 7, 2026
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cogentix Medical, Inc.**
Location	Orangeburg, NY, US
Contact	Chanrasmey White
510(k) history	2 submissions · 2 cleared · 2018-2026