

K253293 VitaloJAK Clinic (Model 7100)Dec 3, 2025
65 days to decisionK253293 · Product code: **DSH** · Anesthesiology
Source: <https://www.510kdatabase.net/k253293/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 29, 2025
Decision date	Dec 3, 2025
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vitalograph , Ltd.
Location	Mchenry, IL, US
Contact	James O'Keefe
510(k) history	17 submissions · 17 cleared · 1979-2025

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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

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