FDA 510(k) Premarket Notification

K254265 Helion Viewer Suite

CLEARED

May 27, 2026
148 days to decision

K254265 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k254265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 30, 2025
Decision date	May 27, 2026
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Videomed Srl (a Baxter Healthcare Corp company)**
Location	Limena (Pd), IT
Contact	Dania Di Pietro Paolo
510(k) history	1 submissions · 1 cleared · 2026-2026