

K254265 Helion Viewer SuiteMay 27, 2026
148 days to decisionK254265 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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