

**K250005 Clever One**May 23, 2025  
141 days to decisionK250005 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k250005/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 2, 2025
Decision date	May 23, 2025
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ewoosoft Co., Ltd.</b>
Location	Houston, TX, US
Contact	Hyeonguk Kang
510(k) history	31 submissions · 31 cleared · 2013-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250005/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026