

**K131616 EZ3D-I, E3**Aug 29, 2013  
87 days to decisionK131616 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k131616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 3, 2013
Decision date	Aug 29, 2013
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ewoosoft Co., Ltd.</b>
Location	Houston, TX, US
Contact	DAVE KIM
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/k131616/> 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 17, 2026