

**K161246 Ez3D-i / E3**May 31, 2016  
28 days to decisionK161246 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k161246/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 3, 2016
Decision date	May 31, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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