

**K260116 CustoMED Viewer**Jun 3, 2026  
140 days to decisionK260116 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k260116/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 14, 2026
Decision date	Jun 3, 2026
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CustoMED , Ltd.</b>
Location	Ramat Gan, IL
Contact	Or Benifla
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>LDP Consulting</b>
Contact	Esther Kott

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)

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