

**K173041 3DIEMME RealGUIDE**Dec 20, 2018  
448 days to decisionK173041 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k173041/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 28, 2017
Decision date	Dec 20, 2018
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3Diemme , Ltd.</b>
Location	Cantu, IT
Contact	Alessandro Montroni
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Registar Corp</b>
Contact	Lara Luzak

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173041/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026