

**K161518 PACS CORE/ENCORE**Aug 17, 2016  
76 days to decisionK161518 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k161518/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 2, 2016
Decision date	Aug 17, 2016
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Compania Mexicana DE Radiologia Cgr, S.A. DE C.V.</b>
Location	Denton, TX, US
Contact	Felipe Cuaranta Monroy
510(k) history	4 submissions · 4 cleared · 2013-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161518/> 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 June 18, 2026