

**K192508 Medsynapse Ris Pacs & Medsynapse VNA**Nov 22, 2019  
71 days to decisionK192508 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k192508/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 12, 2019
Decision date	Nov 22, 2019
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medsynaptic Private, Ltd.</b>
Location	Naples, FL, US
Contact	Ashish Dhawad
510(k) history	3 submissions · 3 cleared · 2009-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

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/k192508/> 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 19, 2026