

**K083423 COLONCAD API 3.1**May 17, 2011  
909 days to decisionK083423 · Product code: **NWE** · Radiology  
Source: <https://www.510kdatabase.net/k083423/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colon Computed Tomography System, Computer Aided Detection (NWE)
Date received	Nov 19, 2008
Decision date	May 17, 2011
Days to decision	909 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicsight Plc</b>
Location	London, GB
Contact	AMARJIT GILL
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083423/> 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 May 17, 2026