

**K161601 Dynamika**May 17, 2017  
342 days to decisionK161601 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k161601/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Jun 9, 2016                                  |
| Decision date         | May 17, 2017                                 |
| Days to decision      | 342 days                                     |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Image Analysis Limited</b>         |
| Location       | London, GB                            |
| Contact        | Mark Hinton                           |
| 510(k) history | 1 submissions · 1 cleared · 2017-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161601/> 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 16, 2026