

**K253532 TruSPECT Processing Station**Dec 30, 2025  
47 days to decisionK253532 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k253532/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Special  |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received         | Nov 13, 2025   |
| Decision date         | Dec 30, 2025   |
| Days to decision      | 47 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|--|
| Company        | <b>Spectrum Dynamics Medical, Ltd.</b> |
| Location       | North Industrial Park. Caesarea, IL    |
| Contact        | Igor Naroditsky                        |
| 510(k) history | 8 submissions · 8 cleared · 2016-2026  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253532/> 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 14, 2026