

**K202882 Affinity**Dec 23, 2020  
86 days to decisionK202882 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k202882/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received         | Sep 28, 2020                                 |
| Decision date         | Dec 23, 2020                                 |
| Days to decision      | 86 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Hermes Medical Solutions AB</b>      |
| Location       | Stockholm, SE                           |
| Contact        | Joakim Arwidson                         |
| 510(k) history | 16 submissions · 16 cleared · 2012-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202882/> 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 26, 2026