

**K232096 Transpara Density 1.0.0**Dec 11, 2023  
151 days to decisionK232096 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k232096/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received         | Jul 13, 2023   |
| Decision date         | Dec 11, 2023   |
| Days to decision      | 151 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Screenpoint Medical B.V.</b>       |
| Location       | Nijmegen, NL                          |
| Contact        | Robin Barwegen                        |
| 510(k) history | 7 submissions · 7 cleared · 2018-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232096/> 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