

K101013 MODIFICATION TO SCINTRON IVJun 7, 2010
56 days to decisionK101013 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k101013/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received | Apr 12, 2010 |
| Decision date | Jun 7, 2010 |
| Days to decision | 56 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Miegmbh |
| Location | Elk Grove Village, IL, US |
| Contact | NORMAN VON HOLLEN |
| 510(k) history | 4 submissions · 4 cleared · 2010-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101013/> Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026