

**K945580 DSP OPTION**Jan 30, 1995  
77 days to decisionK945580 · Product code: **IZJ** · Radiology  
Source: <https://www.510kdatabase.net/k945580/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | Camera, X-ray, Fluorographic, Cine Or Spot (IZJ) |
| Date received         | Nov 14, 1994                                     |
| Decision date         | Jan 30, 1995                                     |
| Days to decision      | 77 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Philips Medical Systems (Cleveland), Inc.</b> |
| Location       | Mchenry, IL, US                                  |
| Contact        | ROBERT L TUROCY                                  |
| 510(k) history | 190 submissions · 190 cleared · 1977-2017        |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945580/> 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