

K893637 MC125L-50 SHIMADZU MOBILE X-RAY SYSTEMJul 20, 1989
69 days to decisionK893637 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k893637/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Mobile (IZL) |
| Date received | May 12, 1989 |
| Decision date | Jul 20, 1989 |
| Days to decision | 69 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Shimadzu Medical Systems |
| Location | Gardena, CA, US |
| Contact | DE MINT |
| 510(k) history | 90 submissions · 90 cleared · 1989-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893637/>; 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 May 18, 2026