

K921116 PX-100 PORTABLE X-RAY GENERATOROct 5, 1992
210 days to decisionK921116 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k921116/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Mobile (IZL) |
| Date received | Mar 9, 1992 |
| Decision date | Oct 5, 1992 |
| Days to decision | 210 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Acoma Medical Imaging, Inc. |
| Location | Wheeling, IL, US |
| Contact | JAMES LAMBRECHT |
| 510(k) history | 13 submissions · 13 cleared · 1989-1998 |

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