

K915227 GEN-X 800/500Jan 9, 1992
50 days to decisionK915227 · Product code: **IZO** · Radiology
Source: <https://www.510kdatabase.net/k915227/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Generator, High-voltage, X-ray, Diagnostic (IZO) |
| Date received | Nov 20, 1991 |
| Decision date | Jan 9, 1992 |
| Days to decision | 50 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Swiss Ray Medical Systems |
| Location | Mobile, AL, US |
| Contact | MICHAEL W SCOTT |
| 510(k) history | 3 submissions · 3 cleared · 1992-1992 |

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