FDA 510(k) Premarket Notification

# K820178 PI808 MOBILE C-ARM IMAGE INTENSIFIER

**CLEARED**

Mar 4, 1982
41 days to decision

K820178 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k820178/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Fluoroscopic, Image-intensified (JAA) |
| Date received | Jan 22, 1982 |
| Decision date | Mar 4, 1982 |
| Days to decision | 41 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Precise Optics** |
| Location | Mchenry, IL, US |
| 510(k) history | 13 submissions · 13 cleared · 1979-2003 |