FDA 510(k) Premarket Notification

# K801408 CINESCOPE III

**CLEARED**

Jul 28, 1980
42 days to decision

K801408 · Product code: **IZO** · Radiology
Source: https://www.510kdatabase.net/k801408/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Generator, High-voltage, X-ray, Diagnostic (IZO) |
| Date received | Jun 16, 1980 |
| Decision date | Jul 28, 1980 |
| Days to decision | 42 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Philips Medical Systems (Cleveland), Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 190 submissions · 190 cleared · 1977-2017 |