

K965013 DIGISCOPE RX-2 (9 OPTION)Jan 17, 1997
32 days to decisionK965013 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k965013/>**SUBMISSION DETAILS**

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|-----------------------|-----------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Image-intensified Fluoroscopic X-ray System, Mobile (OXO) |
| Date received | Dec 16, 1996 |
| Decision date | Jan 17, 1997 |
| Days to decision | 32 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medirex, Inc. |
| Location | Newtown, MA, US |
| Contact | YAEL RUBIN |
| 510(k) history | 3 submissions · 3 cleared · 1996-1997 |

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