

K190024 Smart-CSep 27, 2019
263 days to decisionK190024 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k190024/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Image-intensified Fluoroscopic X-ray System, Mobile (OXO) |
| Date received | Jan 7, 2019 |
| Decision date | Sep 27, 2019 |
| Days to decision | 263 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Turner Imaging Systems, Inc. |
| Location | Orem, UT, US |
| Contact | Michael Drake |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

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