

K170909 Infinix INFX-8000V, V6.40Jun 16, 2017
80 days to decisionK170909 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k170909/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | Mar 28, 2017 |
| Decision date | Jun 16, 2017 |
| Days to decision | 80 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Toshiba Medical Systems Corporation |
| Location | Otawara-Shi, JP |
| Contact | Paul Biggins |
| 510(k) history | 2 submissions · 2 cleared · 2017-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170909/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026