FDA 510(k) Premarket Notification

# K103050 DX-D 300

**CLEARED**

Oct 29, 2010
14 days to decision

K103050 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k103050/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Stationary (KPR) |
| Date received | Oct 15, 2010 |
| Decision date | Oct 29, 2010 |
| Days to decision | 14 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Agfa Healthcare N.V.** |
| Location | Mortsel, BE |
| Contact | PHIL CUSCUNA |
| 510(k) history | 27 submissions · 27 cleared · 2009-2025 |