FDA 510(k) Premarket Notification

# K080784 WBR XPRESS.CARDIAC, WBR XPRESS.BONE

**CLEARED**

Apr 2, 2008
13 days to decision

K080784 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k080784/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received | Mar 20, 2008 |
| Decision date | Apr 2, 2008 |
| Days to decision | 13 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | WBR XACT.CARDIAC, WBR XACT.BONE |

## APPLICANT

| | |
|---|---|
| Company | **Ultraspect , Ltd.** |
| Location | Haifa, IL |
| Contact | DAN LAOR |
| 510(k) history | 6 submissions · 6 cleared · 2004-2011 |