

K080784 WBR XPRESS.CARDIAC, WBR XPRESS.BONEApr 2, 2008
13 days to decisionK080784 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k080784/>**SUBMISSION DETAILS**

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080784/>; 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 17, 2026