

K012097 VORTEXJul 12, 2001
7 days to decisionK012097 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k012097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 5, 2001
Decision date	Jul 12, 2001
Days to decision	7 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Ultravisual Medical Systems
Location	San Leandro, CA, US
Contact	GARY J ALLSEBROOK
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012097/> 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 19, 2026