

K043097 3VISEONNov 19, 2004
10 days to decisionK043097 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k043097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 9, 2004
Decision date	Nov 19, 2004
Days to decision	10 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	3Mensio Medical Imaging BV
Location	Denton, TX, US
Contact	CARL ALLETTO
510(k) history	2 submissions · 2 cleared · 2004-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043097/> 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 18, 2026