

**K946334 GALEN**Mar 23, 1995  
84 days to decisionK946334 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k946334/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Dec 29, 1994
Decision date	Mar 23, 1995
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medimage, Inc.</b>
Location	Ann Arbor, MI, US
Contact	WILLIAM C FORGACS
510(k) history	3 submissions · 3 cleared · 1992-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946334/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026