

**K961597 GATED MIBI 3-D EJECTION FRACTION PROCESSING**Sep 4, 1996  
133 days to decisionK961597 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k961597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Apr 24, 1996
Decision date	Sep 4, 1996
Days to decision	133 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trionix Research Laboratory, Inc.</b>
Location	Twinsburg, OH, US
Contact	CHUN B LIM
510(k) history	16 submissions · 16 cleared · 1988-1997

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