

K964438 511 KEV COLLIMATORMay 29, 1997
205 days to decisionK964438 · Product code: **KPS** · Radiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Nov 5, 1996
Decision date	May 29, 1997
Days to decision	205 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trionix Research Laboratory, Inc.
Location	Twinsburg, OH, US
Contact	DAPHNE REED
510(k) history	16 submissions · 16 cleared · 1988-1997

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