FDA 510(k) Premarket Notification

K130269 ECAT SCINTRON PET

CLEARED

Apr 19, 2013
74 days to decision

K130269 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k130269/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Feb 4, 2013
Decision date	Apr 19, 2013
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Miegmbh**
Location	Elk Grove Village, IL, US
Contact	THOMAS KUEHL
510(k) history	4 submissions · 4 cleared · 2010-2020