FDA 510(k) Premarket Notification

K101013 MODIFICATION TO SCINTRON IV

CLEARED

Jun 7, 2010
56 days to decision

K101013 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k101013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Apr 12, 2010
Decision date	Jun 7, 2010
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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