FDA 510(k) Premarket Notification

K091747 FLAATZ 500

CLEARED

Jul 1, 2009
15 days to decision

K091747 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k091747/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jun 16, 2009
Decision date	Jul 1, 2009
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Drtech Corp.**
Location	Seongnam-Shi, Gyeonggi-Do, KR
Contact	BEOM-JIN MOON
510(k) history	6 submissions · 6 cleared · 2008-2014