FDA 510(k) Premarket Notification

K012238 DOSERIGHT

CLEARED

Oct 1, 2001
76 days to decision

K012238 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k012238/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 17, 2001
Decision date	Oct 1, 2001
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems North America Co.**
Location	Shelton, CT, US
Contact	FRANK GIANELLI
510(k) history	24 submissions · 24 cleared · 2001-2010