FDA 510(k) Premarket Notification

K171183 OmniTom

CLEARED

Aug 18, 2017
116 days to decision

K171183 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k171183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 24, 2017
Decision date	Aug 18, 2017
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neurologica Corporation**
Location	Danvers, MA, US
Contact	Ninad Gujar
510(k) history	8 submissions · 8 cleared · 2005-2025