FDA 510(k) Premarket Notification

K162743 ViewPoint 6

CLEARED

Nov 22, 2016
53 days to decision

K162743 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k162743/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 30, 2016
Decision date	Nov 22, 2016
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Medical Systems Ultrasound and Primary Care Diagnostics**
Location	Wauwatosa, WI, US
Contact	TRACEY ORTIZ
510(k) history	64 submissions · 64 cleared · 2015-2026