FDA 510(k) Premarket Notification

K161959 ClearView cCAD

CLEARED

Dec 28, 2016
163 days to decision

K161959 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k161959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 18, 2016
Decision date	Dec 28, 2016
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Clearview Diagnostics, Inc.**
Location	Piscataway, NJ, US
Contact	Christine Podilchuk
510(k) history	2 submissions · 2 cleared · 2014-2016