FDA 510(k) Premarket Notification

K180332 17HK700G-W

CLEARED

Jun 8, 2018
122 days to decision

K180332 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k180332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Feb 6, 2018
Decision date	Jun 8, 2018
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lg Electronics**
Location	Austin, TX, US
Contact	Jinhwan Jun
Website	http://www.lg.com/
510(k) history	5 submissions · 5 cleared · 2014-2019

LG Electronics is a global consumer electronics manufacturer with a manufacturing facility in Austin, US. The company produces televisions, audio equipment, home appliances, computing devices, and climate control systems. LG Electronics has received FDA 510(k) clearances from total submissions. The company's cleared devices span radiology and general and plastic surgery categories, with additional activity in cardiovascular devices. The regulatory record spans from 2014 to 2019. This company is inactive in the FDA 510(k) clearance process, with no submissions recorded in ...