FDA 510(k) Premarket Notification

K133997 LG SMARTHEALTH

CLEARED

Nov 21, 2014
329 days to decision

K133997 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k133997/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Dec 27, 2013
Decision date	Nov 21, 2014
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lg Electronics**
Location	Austin, TX, US
Contact	DIANE SUDDUTH
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 ...