

K191188 ASHK100GMay 30, 2019
27 days to decisionK191188 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k191188/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | May 3, 2019 |
| Decision date | May 30, 2019 |
| Days to decision | 27 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 ...