FDA 510(k) Premarket Notification

K101691 LIFELINES PHOTIC STIMULATOR

CLEARED

Aug 10, 2010
55 days to decision

K101691 · Product code: **GWE** · Neurology
Source: https://www.510kdatabase.net/k101691/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	Jun 16, 2010
Decision date	Aug 10, 2010
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifelines , Ltd.**
Location	Crofton, MD, US
Contact	E. J AMITH
Website	http://llines.com/
510(k) history	4 submissions · 4 cleared · 2001-2018