FDA 510(k) Premarket Notification

K211974 LED PHOTIC System

CLEARED

Sep 23, 2021
90 days to decision

K211974 · Product code: **GWE** · Neurology
Source: https://www.510kdatabase.net/k211974/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	Jun 25, 2021
Decision date	Sep 23, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Micromed S.P.A.**
Location	Mogliano Veneto (Tv), IT
Contact	Nicola Rizzo
510(k) history	4 submissions · 4 cleared · 2008-2021