FDA 510(k) Premarket Notification

K183110 LIVIA

CLEARED

May 4, 2020
543 days to decision

K183110 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k183110/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Nov 8, 2018
Decision date	May 4, 2020
Days to decision	543 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lifecare , Ltd.**
Location	Kfar Saba, IL
Contact	Amnon Nahum Sharon
510(k) history	3 submissions · 3 cleared · 2001-2020

REGULATORY CONSULTANT

Consulting firm	**Cohen, Tauber, Spievack & Wagner**
Contact	Irving L. Wiesen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03064945

The Effectiveness and Safety of LIVIA® Transcutaneous Electrical Nerve Stimulation (TENS) in Women Suffering From Primary Dysmenorrhea.

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	63 patients (actual)
Study sites	1 site
Condition studied	Dysmenorrhea
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Quadruple
Completion date	Apr 25, 2018
Sponsor	iPulse Medical Ltd. (Livia) (Industry)

Primary outcome

The difference between the reported Visual Analogue Scale before and after applying the device (active or sham).

Secondary outcome

Usage of pain relievers during the menstrual period

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03064945