FDA 510(k) Premarket Notification

K173681 reSET-O

CLEARED

Dec 10, 2018
374 days to decision

K173681 · Product code: **PWE** · Neurology
Source: https://www.510kdatabase.net/k173681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Behavioral Therapy Device For Substance Use Disorders (PWE)
Date received	Dec 1, 2017
Decision date	Dec 10, 2018
Days to decision	374 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pear Therapeutics, Inc.**
Location	Boston, MA, US
Contact	Yuri Maricich
510(k) history	3 submissions · 2 cleared · 2017-2020