FDA 510(k) Premarket Notification

K173589 Prizma

CLEARED

Nov 30, 2018
375 days to decision

K173589 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k173589/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Nov 20, 2017
Decision date	Nov 30, 2018
Days to decision	375 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**G-Medical Innovations , Ltd.**
Location	Rehovot, IL
Contact	N. Epstein
510(k) history	2 submissions · 2 cleared · 2017-2018

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Jonathan Kahan

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

CLINICAL EVIDENCE - NCT03340441

Prizma Device Temperature Measurement

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	300 patients (estimated)
Study sites	1 site
Condition studied	Temperature Change, Body
Study type	Observational
Completion date	Dec 30, 2017
Sponsor	G Medical Innovations Ltd. (Industry)

Primary outcome

Temperature measurement

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03340441