

K201302 LiveOneMay 4, 2022
719 days to decisionK201302 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k201302/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	May 15, 2020
Decision date	May 4, 2022
Days to decision	719 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Livemetric (Medical) S.A.
Location	Luxemburg, LU
Contact	Chen Botvin Moshe
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT03919136

Wrist Worn Blood Pressure Measurement

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	40 patients (estimated)
Study sites	3 sites
Condition studied	Blood Pressure; Heart Failure; Advanced Heart Failure; Heart Failure?Congestive
Study type	Observational
Completion date	Oct 1, 2019
Sponsor	LiveMetric S.A. (Other)

Primary outcome**Non-Oscillometric Blood Pressure Wrist Worn Data Acquisition and Analysis**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03919136

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