FDA 510(k) Premarket Notification

K214073 eWave Monitor

CLEARED

Oct 20, 2022
297 days to decision

K214073 · Product code: **DSH** · Cardiovascular
Source: https://www.510kdatabase.net/k214073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Dec 27, 2021
Decision date	Oct 20, 2022
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Wearlinq, Inc.**
Location	San Francisco, CA, US
Contact	Konrad Morzkowski
510(k) history	1 submissions · 1 cleared · 2022-2022