

K181541 Connect App for iHealth Next, iHealth React Native SDK, iHealth React Native Library SDK, iHealth Library SDK, iHealth Native SDKApr 16, 2019
309 days to decisionK181541 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k181541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jun 11, 2018
Decision date	Apr 16, 2019
Days to decision	309 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Andon Health Co, Ltd.
Location	Tiajin, CN
Contact	Yi Liu
510(k) history	92 submissions · 92 cleared · 2008-2025

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