FDA 510(k) Premarket Notification

K162616 Wrist Type Blood Pressure Monitor

CLEARED

Mar 9, 2018
535 days to decision

K162616 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k162616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 20, 2016
Decision date	Mar 9, 2018
Days to decision	535 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xuzhou Yongkang Electronic Science Technology Co., Ltd.**
Location	Xuzhou, CN
Contact	YanLi Li
510(k) history	6 submissions · 6 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**Beijing Believe Technology Service Co., Ltd.**
Contact	Ray Wang

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