FDA 510(k) Premarket Notification

K173197 Reusable NIBP Cuff

CLEARED

Aug 21, 2018
323 days to decision

K173197 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k173197/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Oct 2, 2017
Decision date	Aug 21, 2018
Days to decision	323 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orantech, Inc.**
Location	Shenzhen, CN
Contact	Yunxi Xiong
510(k) history	5 submissions · 5 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Kevin Wang

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