

K173197 Reusable NIBP CuffAug 21, 2018
323 days to decisionK173197 · 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](https://accessdata.fda.gov)

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