FDA 510(k) Premarket Notification

CLEARED

K190893 Non-invasive Hemodynamic Blood Pressure Monitor

Aug 7, 2019
124 days to decision

K190893 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k190893/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 5, 2019
Decision date	Aug 7, 2019
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vita-Course Technologies Co., Ltd.**
Location	Shenzhen, CN
Contact	Kezheng Ma
510(k) history	1 submissions · 1 cleared · 2019-2019

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190893/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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