

K173028 BPro BT Ambulatory Blood Pressure Monitoring System with BProSoft BT PC Software

Jun 21, 2018
266 days to decision

K173028 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k173028/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 28, 2017
Decision date	Jun 21, 2018
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Healthstats International Pte. , Ltd.
Location	Eagle, WI, US
Contact	Ngak Hwee Chua
510(k) history	7 submissions · 7 cleared · 2005-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k173028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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