FDA 510(k) Premarket Notification

K190133 Full Automatic (NIBP) Blood Pressure Monitor-HL158UB

CLEARED

Jun 13, 2019
136 days to decision

K190133 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k190133/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 28, 2019
Decision date	Jun 13, 2019
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Health & Life Co., Ltd.**
Location	Taipei Hsien, TW
Contact	JS Hsu
510(k) history	60 submissions · 60 cleared · 1999-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190133/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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