

K211127 Full Automatic (NIBP) Blood Pressure Monitor, Model HL858DMSep 8, 2021
145 days to decisionK211127 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k211127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 16, 2021
Decision date	Sep 8, 2021
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211127/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026