

K130564 FULL AUTOMATIC (NIBP) BLOOD PRESSURE MONITORJun 19, 2013
107 days to decisionK130564 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k130564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Mar 4, 2013
Decision date	Jun 19, 2013
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130564/> 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 24, 2026