

K243115 Upper Arm Electronic Blood Pressure Monitor (U87Y series (models including U80Y, U81Y, U82Y,U83Y,U86Y U80N, U81NH), U86E series (including U82E, U80E, U80EH, U81E, U83E, U85E, U80L, U87E), U81X series (including U81X, U80X, U82X, U83X, U81D, U82D, U83D, U81RH, U82RH) and U83Z series (including U83Z, U80Z, U81Z, U82Z, U85Z, U86Z and U87Z))

Feb 21, 2025
144 days to decision

K243115 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k243115/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 30, 2024
Decision date	Feb 21, 2025
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Urion Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Janice Ou
510(k) history	7 submissions · 7 cleared · 2015-2026
