

K160019 U80 Series Upper Arm Electronic Blood Pressure MonitorApr 22, 2016
108 days to decisionK160019 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k160019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 5, 2016
Decision date	Apr 22, 2016
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160019/> 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