

K253152 BP1000 Ultra-Compact Fingertip Blood Pressure Monitor (BP1000)

May 6, 2026
222 days to decision

K253152 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k253152/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 26, 2025
Decision date	May 6, 2026
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Biozen, LLC
Location	Oklahoma City, OK, US
Contact	Omer Inan
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k253152/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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