

K230145 ONE-CUFMar 14, 2023
55 days to decisionK230145 · Product code: **DXQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k230145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Jan 18, 2023
Decision date	Mar 14, 2023
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Information Technologies, Inc.
Location	Milwaukee, WI, US
Contact	Jennifer Strauther
510(k) history	31 submissions · 31 cleared · 2010-2026

REGULATORY CONSULTANT

Consulting firm	GE Healthcare
Contact	Michelle Johnson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230145/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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