

K221742 CONNEQT PULSEApr 21, 2023
310 days to decisionK221742 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k221742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 15, 2022
Decision date	Apr 21, 2023
Days to decision	310 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Atcor Medical
Location	West Ryde Nsw, AU
Contact	Toni Hofhine
510(k) history	3 submissions · 3 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	Heyer Regulatory Soilutions
Contact	Sheila Hemeon-Heyer

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/k221742/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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