FDA 510(k) Premarket Notification

CLEARED

K230996 Pursuant Health Kiosk (G1.D5)

Jan 4, 2024
272 days to decision

K230996 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k230996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 7, 2023
Decision date	Jan 4, 2024
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Pursuant Health**
Location	Alpharetta, GA, US
Contact	Leslie Sommers
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Regsolutions, LLC**
Contact	Penny Northcutt

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