FDA 510(k) Premarket Notification

K223905 Vivio® LVEDP System

CLEARED

Oct 6, 2023
282 days to decision

K223905 · Product code: **QUO** · Cardiovascular
Source: https://www.510kdatabase.net/k223905/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Heart Failure Status Indicator (QUO)
Date received	Dec 28, 2022
Decision date	Oct 6, 2023
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Avicena, LLC**
Location	Altadena, CA, US
Contact	Sean Brady
510(k) history	2 submissions · 2 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Qserve Group US**
Contact	Lorry Weaver

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