FDA 510(k) Premarket Notification

K230769 PrevisEA Device

CLEARED

May 19, 2023
60 days to decision

K230769 · Product code: **DQD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Mar 20, 2023
Decision date	May 19, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Entac Medical, Inc.**
Location	Memphis, TN, US
Contact	Buddy Lyons
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Target Health, LLC**
Contact	Adam Harris

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