FDA 510(k) Premarket Notification

K233974 Mucosal Impedance Measurement System

CLEARED

Sep 6, 2024
266 days to decision

K233974 · Product code: **QIS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233974/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal, Mucosal, Electrical Characterization (QIS)
Date received	Dec 15, 2023
Decision date	Sep 6, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alandra Medical Sapi DE CV**
Location	Mexico City, MX
Contact	Montserrat Godinez Garcia
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov