FDA 510(k) Premarket Notification

K222677 Intermittent nelaton catheter for single use

CLEARED

Apr 5, 2023
211 days to decision

K222677 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k222677/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Sep 6, 2022
Decision date	Apr 5, 2023
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hangzhou Jimushi Meditech Co., Ltd.**
Location	Hangzhou, CN
Contact	Fenlong Wu
510(k) history	2 submissions · 2 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**Vee Care (Asia) Limited**
Contact	Wei Shan Hsu

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