

K220722 PVC Hydrophilic Urethral CatheterMay 22, 2023
434 days to decisionK220722 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k220722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Mar 14, 2022
Decision date	May 22, 2023
Days to decision	434 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Well Lead Medical Co., Ltd.
Location	Apollo Beach, FL, US
Contact	Jenny Zhu
510(k) history	17 submissions · 17 cleared · 2009-2025

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