

K212567 PVC Hydrophilic Urethral CatheterDec 7, 2022
478 days to decisionK212567 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k212567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Aug 16, 2021
Decision date	Dec 7, 2022
Days to decision	478 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chengdu Daxan Innovative Medical Tech. Co., Ltd.
Location	Chengdu, CN
Contact	Kevin Huang
510(k) history	2 submissions · 2 cleared · 2022-2025

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