

K220036 Wellead Ureteral CatheterDec 16, 2022
345 days to decisionK220036 · Product code: **KOD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k220036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Jan 5, 2022
Decision date	Dec 16, 2022
Days to decision	345 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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