

K241734 Wellead® Hydrophilic Intermittent Catheter Ready to UseMar 5, 2025
261 days to decisionK241734 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241734/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Jun 17, 2024
Decision date	Mar 5, 2025
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Wellead® Hydrophilic Intermittent Catheter Compact

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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