

**K211814 Wellead Endoscopic Seal**Jan 14, 2022  
217 days to decisionK211814 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211814/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Jun 11, 2021
Decision date	Jan 14, 2022
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Well Lead Medical Co., Ltd.</b>
Location	Apollo Beach, FL, US
Contact	Caroline Gong
510(k) history	17 submissions · 17 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211814/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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