

K161110 ClearPetra Suction-Evacuation SheathOct 12, 2016
175 days to decisionK161110 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k161110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Apr 20, 2016
Decision date	Oct 12, 2016
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161110/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026