

K162340 Stomach TubeOct 11, 2017
415 days to decisionK162340 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162340/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received | Aug 22, 2016 |
| Decision date | Oct 11, 2017 |
| Days to decision | 415 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Well Lead Medical Co., Ltd. |
| Location | Apollo Beach, FL, US |
| Contact | HUANG KAI GEN |
| 510(k) history | 17 submissions · 17 cleared · 2009-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162340/> 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