

K123205 ESOPHAGEAL TTS STENTOct 9, 2013
362 days to decisionK123205 · Product code: **ESW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k123205/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Esophageal (ESW) |
| Date received | Oct 12, 2012 |
| Decision date | Oct 9, 2013 |
| Days to decision | 362 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Taewoong Medical Co., Ltd. |
| Location | Gyeonggi-Do, KR |
| Contact | Calley Herzog |
| 510(k) history | 15 submissions · 11 cleared · 2005-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123205/> 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 26, 2026