

**K211706 Esophageal TTS Stent**Oct 8, 2021  
127 days to decisionK211706 · Product code: **ESW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k211706/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Prosthesis, Esophageal (ESW)       |
| Date received         | Jun 3, 2021                        |
| Decision date         | Oct 8, 2021                        |
| Days to decision      | 127 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Taewoong Medical Co., Ltd.</b>       |
| Location       | Gyeonggi-Do, KR                         |
| Contact        | Jennifer Moyer                          |
| 510(k) history | 15 submissions · 11 cleared · 2005-2026 |

**REGULATORY CONSULTANT**

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|-----------------|---|
| Consulting firm | <b>Biologics Consulting Group, Inc.</b> |
| Contact         | Jennifer Moyer                          |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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