

**K080782 NITI-S ESOPHAGEAL STENT**Jan 30, 2009  
317 days to decisionK080782 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k080782/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Prosthesis, Esophageal (ESW)
Date received	Mar 19, 2008
Decision date	Jan 30, 2009
Days to decision	317 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080782/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026