

K113551 ESOPHAGEAL TTS STENTFeb 14, 2012
75 days to decisionK113551 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k113551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Dec 1, 2011
Decision date	Feb 14, 2012
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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