

K041648 NITI-S STENT & INTRODUCER, MODEL EOXXXXApr 28, 2005
315 days to decisionK041648 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k041648/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Esophageal (ESW) |
| Date received | Jun 17, 2004 |
| Decision date | Apr 28, 2005 |
| Days to decision | 315 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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