

K260962 SphincterotomeMay 21, 2026
59 days to decisionK260962 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k260962/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Mar 23, 2026
Decision date	May 21, 2026
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taewoong Medical Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	Yongjin "Jeff" Kim
510(k) history	16 submissions · 12 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group, Inc.
Contact	Matthew Krueger

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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