

**K223256 Optimos™ Cystotome**Apr 5, 2023  
166 days to decisionK223256 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k223256/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Oct 21, 2022
Decision date	Apr 5, 2023
Days to decision	166 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	Yongjin Jeff Kim
510(k) history	15 submissions · 11 cleared · 2005-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biologics Consulting Group, Inc.</b>
Contact	Christy Foreman

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223256/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026