

K223266 Hilzo Esophageal StentsJan 16, 2024
449 days to decisionK223266 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k223266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Oct 24, 2022
Decision date	Jan 16, 2024
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thoracent, Inc.
Location	Huntington, NY, US
Contact	Brian Lynch
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	ProMedoss, Inc.
Contact	Bosmat Friedman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223266/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026