

**K242336 hygh-tec Drainage II**Jan 17, 2025  
163 days to decisionK242336 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k242336/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Aug 7, 2024
Decision date	Jan 17, 2025
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Amb Medtec</b>
Location	Wagh?usel, DE
Contact	Frank Gehres
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Nilo Medical Consulting Group, LLC</b>
Contact	Michael Nilo

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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