

K234145 ViSiGi 3D Gastric Sizing TubeJan 26, 2024
28 days to decisionK234145 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k234145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Dec 29, 2023
Decision date	Jan 26, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Laboratories
Location	Mchenry, IL, US
Contact	Nathan Simasek
Website	http://www.boehringerlabs.com
510(k) history	38 submissions · 38 cleared · 1976-2024

Boehringer Laboratories is a family-owned American medical technology company headquartered in Phoenixville, Pennsylvania, with operations in McHenry, US. The company specializes in respiratory therapy and minimally invasive surgical devices. Boehringer Laboratories has maintained a strong FDA 510(k) regulatory record since 1976. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. Recent clearances span 2024, demonstrating continued active development. The company's portfolio focuses primarily on anesthesiology devices, inclu...

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Device record: <https://www.510kdatabase.net/k234145/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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