FDA 510(k) Premarket Notification

K234033 ViSiGi LUX (5332)

CLEARED

May 6, 2024
138 days to decision

K234033 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k234033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Dec 20, 2023
Decision date	May 6, 2024
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ViSiGi LUX (5336); ViSiGi LUX (5340)

APPLICANT

Company	**Boehringer Laboratories, LLC**
Location	Phoenixville, PA, US
Contact	Ondrej Nikel
Website	http://www.boehringerlabs.com
510(k) history	5 submissions · 5 cleared · 2013-2025

Boehringer Laboratories, LLC is a leader in high-quality, precision medical devices with a manufacturing facility in Phoenixville, US. Founded in 1972, the company develops and manufactures innovative surgical and clinical care products serving hospitals and healthcare systems globally across 38 countries. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2013. Boehringer's devices span General & Plastic Surgery and Gastroenterology & Urology specialties, with recent cleared products including surgical retractors, tissue re...