

K203133 ENvizion Medical ENvue ENvizion Medical Enteral Feeding TubeMar 24, 2021
156 days to decisionK203133 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k203133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Oct 19, 2020
Decision date	Mar 24, 2021
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Envizion Medical , Ltd.
Location	Tel Aviv, IL
Contact	Doron Besser
510(k) history	3 submissions · 3 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Evergreen Research, Inc.
Contact	John Mann

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/k203133/> 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 27, 2026