

**K191387 ENvizion Medical ENVue SYSTEM, ENvizion Medical
Enteral Feeding Tube**

Jun 14, 2019
21 days to decision

K191387 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191387/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	May 24, 2019
Decision date	Jun 14, 2019
Days to decision	21 days
Third-party review	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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191387/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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