March 24, 2021

ENvizion Medical Ltd.
% John Mann
Director
Evergreen Research, Inc.
433 Park Point Drive, Suite 140
Golden, CO 80401

Re: K203133
Trade/Device Name: ENvizion Medical ENvue
ENvizion Medical Enteral Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT, PIF
Dated: October 15, 2020
Received: October 19, 2020

Dear John Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203133

Device Name
ENvizion Medical ENvue
ENvizion Medical Enteral Feeding Tube

Indications for Use *(Describe)*
The ENvizion Medical ENvue System is designed to aid qualified operators in the placement of the ENvizion Medical Enteral Feeding Tube from 8 Fr to 12 Fr into the stomach or small intestine of adult patients requiring enteral feeding. The ENvizion Medical ENvue System is intended as an adjunct to current placement practices for assisting clinical practitioners who place feeding tubes.

The ENvizion Medical Enteral Feeding Tube (EFT) has been specifically designed for use with the ENvue System and is intended for placement in the stomach or small intestine. It is intended for use in adult patients who require intermittent or continuous feeding via the oro/nasoenteric route. The EFT is intended only to be used with a feeding pump and is not compatible with gravity-based feeding bags.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

INTRODUCTION:

This document contains the 510(k) Summary for the ENvizion Medical ENvue and ENvizion Medical Enteral Feeding Tube. The content of this summary is based on the requirements set forth in 21 CFR 807.92(c).

SUBMITTER INFORMATION

Applicant / Manufacturer Name and Address	ENvizion Medical Ltd. 7 Haarad Street Tel Aviv, 6971060 Israel Phone +972 72-2288240
510(k) contact person	John Mann Director Evergreen Research, Inc. 433 Park Point Drive, Suite 140 Golden CO 80401 jmann@evergreenresearch.com (720) 287-8751
Date prepared	March 12, 2021

DEVICE IDENTIFICATION

Trade names	ENvizion Medical ENvue ENvizion Medical Enteral Feeding Tube
Common name	Gastrointestinal tubes and accessories
Classification name	Gastrointestinal tubes and accessories
Regulation Number	21 CFR Part 876.5980
Classification	Class II
Product Code	KNT, PIF

PREDICATE DEVICE

Trade names	ENvizion Medical ENvue ENvizion Medical Enteral Feeding Tube
510(k) number	K191387

DEVICE DESCRIPTION

The ENvizion Medical ENvue System is an electro-mechanical device with embedded software designed to aid in the placement of the ENvizion Medical Enteral Feeding Tube (with or without stylet), which is an enteral feeding tube placed into the stomach or small intestine of patients requiring enteral feeding. The ENvue System tracks the Enteral Feeding Tube (EFT) as it progresses through the oro/nasoenteric route down the esophagus, into the stomach and to the small intestine anatomy and displays the placement pathway in real time during placement. Once the placement is completed, the user disconnects the ENvue from the EFT. The EFT connects to a feeding pump using ENFit connections.

This 510(k) notification adds an 8 Fr EFT with a stainless-steel stylet and changes the input source for patient posture from using the plate sensor to the marking stylus. The plate sensor has been removed from the system.

INDICATIONS FOR USE

The ENvizion Medical ENvue System is designed to aid qualified operators in the placement of the ENvizion Medical Enteral Feeding Tube from 8 Fr to 12 Fr into the stomach or small intestine of adult patients requiring enteral feeding. The ENvizion Medical ENvue System is intended as an adjunct to current placement practices for assisting clinical practitioners who place feeding tubes.

The ENvizion Medical Enteral Feeding Tube (EFT) has been specifically designed for use with the ENvue System and is intended for placement in the stomach or small intestine. It is intended for use in adult patients who require intermittent or continuous feeding via the oro/nasoenteric route. The EFT is intended only to be used with a feeding pump and is not compatible with gravity-based feeding bags.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

Substantial Equivalence: The modified version of the ENvizion Medical ENvue with ENvizion Medical Enteral Feeding Tubes is substantially equivalent to the unmodified version of the device (ENvizion Medical ENvue with ENvizion Medical Enteral Feeding Tubes).

The 510(k) Substantial Equivalence Decision-making Process (detailed) from the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] was followed as described below:

- The ENvue device has the same intended use and the similar indications for use as the Predicate device.
- The ENvue device uses the same fundamental technology as the Predicate device and very similar detailed technological characteristics. Both products use electromagnetic fields and receivers to provide placement pathway of the tube through the patient's naso/oro enteral anatomy.
- The small differences between the ENvue device and the Predicate do not raise new or different questions of safety or effectiveness
    - The biocompatibility of both products' patient contact materials complies with ISO 10993-1 in accordance with FDA guidance related to the application of this standard.
    - Bench testing demonstrates the safety and performance of the 8 Fr EFT and the stylus providing patient posture resulting in no new / significantly modified risks as a result of the modification.

- Clinical evaluation demonstrates the safety and effectiveness of the system using the electromagnetic field and receivers for providing the placement pathway of the tube through the patient's anatomy.

PERFORMANCE DATA

There are no known performance standards for this device.

The Enteral Feeding Tube were verified and validated in accordance with 820.30. The following tests were completed to demonstrate substantial equivalence and that any technological differences do not raise new or different questions of safety and effectiveness. The subject device successfully passed all of the testing and the results demonstrate the device is safe, effective, and performs as well or better than the predicate device.

- Biocompatibility
- Dimensional Inspection
- Visual Inspection
- Liquid Leakage Testing
- Tensile Strength Testing
- Flow Rate Testing
- Extended 30-day Gastric Compatibility
- Tubing Stiffness Comparison
- Shelf-Life Validation
- Simulated Use
- Software validation
- Retrospective clinical evaluation study

To provide confirmatory evidence of the safety and effectiveness of the ENvue device, an on-label, retrospective, pseudonymized clinical evaluation was performed with 50 placements across 48 randomly selected patients (2 of the subjects had 2 placements each). An analysis of the data gathered from the 50 placements showed 100% agreement between the system display and the x-ray position confirmation. A review of the data showed the device performed safely and effectively without any guidance related adverse events.

The device continues to conform to the following voluntary recognized consensus standards:

- BS/EN 1615:2000 – Enteral feeding catheters and enteral giving sets for single use and their connectors. Design and testing.
- BS/EN 1618:1997 – Catheters other than intravascular catheters. Test methods for common properties.
- ANSI/AAMI/ISO 10993-1:2009(R) 2013 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- IEC 60601-1, Ed. 3: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; Corrigendum 1(2006): Corrigendum 2 (2007)

- IEC 60601-1-2 Ed 4.0: Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 62366-1:2015: Medical devices -- Part 1: Application of usability engineering to medical devices
- ISO 80369-3: 2016: Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications

SUBSTANTIAL EQUIVALENCE COMPARISON

Characteristic	ENvizion Medical™ ENvue (Predicate Device)	CORPAK CORFLO Nasoenteric Feeding Tubes (Reference Device)	Modified ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate / Reference Device
510(k) Number	K191387	K821906	N/A	N/A
Regulation Number	21 CFR 876.5980	21 CFR 876.5980	21 CFR 876.5980	Identical to Predicate
Classification Name	Gastrointestinal tube and accessories.	Gastrointestinal tube and accessories.	Gastrointestinal tube and accessories.	Identical to Predicate
Product Classification Code	KNT	KNT	KNT	Identical to Predicate
Regulatory Class	Class II	Class II	Class II	Identical to Predicate

Characteristic	ENvizion Medical™ ENvue (Predicate Device)	CORPAK CORFLO Nasoenteric Feeding Tubes (Reference Device)	Modified ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate / Reference Device
Intended Use	Aids qualified operators in the placement of the of nasoenteral feeding tubes into the stomach or small intestine of patients requiring enteral feeding.	Delivery of nutrition, fluids, and medications to the stomach or bowel	Aids qualified operators in the placement of the of enteral feeding tubes into the stomach or small intestine of patients requiring enteral feeding.	Identical to Predicate
Indications for Use	The ENvizion Medical ENvue System is designed to aid qualified operators in the placement of the ENvizion Medical Enteral Feeding Tube of 10 Fr and 12 Fr into the stomach or small intestine of adult patients requiring enteral feeding. The ENvizion Medical ENvue System is intended as an adjunct to current placement practices for assisting clinical practitioners who place feeding tubes. The ENVIZION MEDICAL Enteral Feeding Tube (EFT) has been specifically designed for use with the ENvue System and is intended for placement in the stomach or small intestine. It is intended for use in adult patients who require intermittent or continuous feeding via the oro/nasoenteric route. The EFT is intended only to be used with a feeding pump and is not compatible with gravity-based feeding bags.	The CORFLO Nasoenteric Feeding Tube is intended for use in those patients who require intermittent or continuous tube feedings via the nasogastric or nasoenteric feeding route.	The ENvizion Medical ENvue System is designed to aid qualified operators in the placement of the ENvizion Medical Enteral Feeding Tube of from 8 Fr to 12 Fr into the stomach or small intestine of adult patients requiring enteral feeding. The ENvizion Medical ENvue System is intended as an adjunct to current placement practices for assisting clinical practitioners who place feeding tubes. The ENVIZION MEDICAL Enteral Feeding Tube (EFT) has been specifically designed for use with the ENvue System and is intended for placement in the stomach or small intestine. It is intended for use in adult patients who require intermittent or continuous feeding via the oro/nasoenteric route. The EFT is intended only to be used with a feeding pump and is not compatible with gravity-based feeding bags.	Substantially Equivalent 8 Fr EFT with stylet are equivalent to the Predicate and Reference Devices *Differences do not raise new or different questions regarding safety or effectiveness*

Characteristic	ENvizion Medical™ ENvue (Predicate Device)	CORPAK CORFLO Nasoenteric Feeding Tubes (Reference Device)	Modified ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate / Reference Device
Operating Principle and design	Rechargeable battery powered electromagnetic (EM) system sensing technology to track and display path of feeding tube using an EM Tracking System, Computer and Display. The EM Transmitter is the Field Generator and the system uses multiple EM Receivers including one integrated in the tube distal tip. A single-use polyurethane radiopaque tube and tip (for X-ray visualization) available with and without stylet. Nutrition is administered with the polymeric tubing providing a fluid path between the nutritional supplement source (i.e. feeding pump) and the stomach or small intestine of the patient.	A single-use polyurethane radiopaque tube and tip (for X-ray visualization). Nutrition is administered with the polymeric tubing providing a fluid path between the nutritional supplement source (e.g. feeding bag or feeding pump) and the stomach or small intestine of the patient.	Rechargeable battery powered electromagnetic (EM) system sensing technology to track and display path of feeding tube using an EM Tracking System, Computer and Display. The EM Transmitter is the Field Generator and the system uses multiple EM Receivers including one integrated in the tube distal tip. A single-use polyurethane radiopaque tube and tip (for X-ray visualization) available with and without stylet. Nutrition is administered with the polymeric tubing providing a fluid path between the nutritional supplement source (i.e. feeding pump) and the stomach or small intestine of the patient.	Substantially equivalent *Differences do not raise new or different questions regarding safety or effectiveness*
Tube Type	Multi Lumen with and without optional stylet	Single lumen with stylet	Multi Lumen with and without optional stylet	Identical to Predicate

Characteristic	ENvizion Medical™ ENvue (Predicate Device)	CORPAK CORFLO Nasoenteric Feeding Tubes (Reference Device)	Modified ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate / Reference Device
Tube Outer Diameter	10 and 12Fr	8 to 12 Fr	8 to 12Fr	Substantially Equivalent 8 Fr EFT with stylet are equivalent to the Reference Devices *Differences do not raise new or different questions regarding safety or effectiveness*
Tube Usable Length	36 to 55 in 91 to 140 cm	36 to 55 in 91 to 140 cm	36 to 55 in 91 to 140 cm	Identical to Predicate
Patient contacting tubing material	Polyurethane	Polyurethane	Polyurethane	Identical to Predicate
Biocompatibility	FDA application of ISO 10993	ISO 10993	FDA application of ISO 10993	Identical to Predicate
Feeding Connector	80369-3 Connector - ENFit	80369-3 Connector - ENFit	80369-3 Connector - ENFit	Identical to Predicate
Sterilization	Non-sterile	Non-sterile	Non-sterile	Identical to Predicate

Characteristic	ENvizion Medical™ ENvue (Predicate Device)	CORPAK CORFLO Nasoenteric Feeding Tubes (Reference Device)	Modified ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate / Reference Device
Target User	Intended for use by physicians, technicians and nutritionists.	Intended for use by physicians, technicians and nutritionists.	Intended for use by physicians, technicians and nutritionists.	Identical to Predicate
Use Environment	Hospitals and other healthcare facilities	Hospitals and other healthcare facilities	Hospitals and other healthcare facilities	Identical to Predicate
Access / Anatomical Site	Oro / Nasoenteric	Nasoenteric	Oro / Nasoenteric	Identical to Predicate
Energy Type – For EFT Tracking	Electromagnetic Field	Electromagnetic Field	Electromagnetic Field	Identical to Predicate
Patient Population	Adults	Adults	Adults	Identical to Predicate

The modified ENvizion Medical ENvue System and Enteral Feeding Tube is substantially equivalent with respect to the indication for use, technological characteristics, target user, and use environment to the following legally marked Predicate devices:

- Predicate: ENvizion Medical ENvue System and Enteral Feeding Tube, K191387
- Reference Device: CORPAK CORFLO Nasoenteric Feeding Tubes, K821906

CONCLUSION

The modified ENvizion Medical ENvue and Enteral Feeding Tube are substantially equivalent to the unmodified version of the ENvizion Medical ENvue System and Enteral Feeding Tube.