February 13, 2019

ENvizion Medical Ltd.
% Clay Anselmo
Principle Consultant
Shriner & Associates
429 Whitepine Creek Road
Trout Creek, MT 59874

Re: K182915
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: II
Product Code: KNT
Dated: January 18, 2019
Received: January 23, 2019

Dear Clay Anselmo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or (301) 796-7100).

Sincerely,

Mark J. Antonino -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K182915

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 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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	Clay Anselmo Principal Quality and Regulatory Consultant Shriner & Associates 429 Whitepine Creek Road Trout Creek, MT 59874 Clay.anselmo@yahoo.com (303) 907-2955
Date prepared	10/11/2018

DEVICE IDENTIFICATION

Trade Names	ENvizion Medical ENvue ENvizion Medical Enteral Feeding Tube
Regulation Name	Gastrointestinal tube and accessories
Product Code Device Name	Tubes, Gastrointestinal (and Accessories)
Regulation Number	21 CFR Part 876.5980
Classification	Class II
Product Code	KNT

PREDICATE DEVICE

Trade names	CORTRAK Enteral Access Device and CORFLO Nasoenteric Feeding Tubes with Electromagnetic Transmitting Stylet
510(k) number	K080679 (CORTRAK Enteral Access Device) K821906 (CORFLO NasoEnteric Feeding Tube)

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, 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.

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.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

Substantial Equivalence: The ENvizion Medical ENvue is substantially equivalent to the CORTRAK Enteral Access Device and CORTRAK CORFLO NasoEnteric feeding tubes with transmitting stylet

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 similar indications for use asthe Predicate device.
- The ENvue device uses the same fundamental technology as the Predicate device and very similar detailed technological solutions as follows: 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 types of 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.
    - Both products have certification to medical device safety standards for 60601-1 Electrical Safety and 60601-1-2 EMC

For a more detailed comparison, refer to the Substantial Equivalence table below.

PERFORMANCE DATA

There are no known performance standards for this device.

The ENvizion Medical ENvue and 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 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
- Liquid Leakage Testing
- Visual Inspection
- Tensile Strength Testing
- Flow Rate Testing
- Tubing Stiffness Comparison
- Simulated Use
- Packaging Validation
- Shelf Life Validation
- Gastric Fluid Compatibility
- Software Validation
- IEC 60601-1 Electrical Safety
- IEC 60601-1-2 Electromagnetic Compatibility (EMC)
- Summative Usability
- Comparative Testing
- MR Compatibility Testing
- Human Clinical Study

To provide confirmatory evidence of the safety and effectiveness of the ENvue device, two clinical studies were executed and the data pooled from 58 subjects. Each of the studies was a prospective, single center, non-randomized clinical trial in subjects that required placement of a enteral feeding tube as a result of their current medical condition. The study included placements through both the oro and naso routes.

An analysis of the data gathered from 54 placements during the clinical study showed no device guidance-related adverse events and no serious adverse events of any kind occurred during the study. There were thirteen alleged device malfunctions; twelve of the thirteen tube placements occurred were determined not to be adverse events per the case report forms. One incident was identified as an adverse event; however, upon further reviewed was determined not to be a serious adverse event and was identified as a manufacturing nonconformance. A review of the CRF's and associated procedural data showed the device performed safely and effectively without any guidance related incidents.

The device has been designed in conformance 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 62304:2015, Medical Device Software – Software Lifecycle Processes
- 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	CORPAK CORTRAK (Predicate Device)	ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate
510(k) Number	K080679 (CORTRAK 2 Enteral Access Device) K821906* (CORFLO Feeding Tube)	K182915	N/A
Regulation Number	21 CFR 876.5980	21 CFR 876.5980	Identical
Classification Name	Gastrointestinal tube and accessories.	Gastrointestinal tube and accessories.	Identical
Product Classification Code	KNT	KNT	Identical
Regulatory Class	Class 2	Class 2	Identical
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.	Aids qualified operators in the placement of the of enteral feeding tubes into the stomach or small intestine of patients requiring enteral feeding.	Identical
Indications for Use	The CORTRAK System is an electrical device designed to aid qualified operators in the placement of the VIASYS MedSystems feeding tubes of 8 FR or greater into the stomach or small bowel of patients requiring enteral feeding. Prior to commencing the delivery of food, confirmation or correct tube placement by acceptable hospital protocol is required.	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.	Substantially Equivalent *Differences do not raise new or different questions regarding safety or effectiveness*

Characteristic	CORPAK CORTRAK (Predicate Device)	ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate
		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.	
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 integrated into the feeding tube distal tip and the EM Receiver is placed externally on the Xiphoid Process. 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). 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	Single lumen	Multi Lumen	Substantially equivalent *Differences do not raise new or different questions*

Characteristic	CORPAK CORTRAK (Predicate Device)	ENvizion Medical™ ENvue (Subject Device)	Comparison to Predicate
			regarding safety or effectiveness
Tube Outer Diameter	8 to 12 Fr	10 and 12Fr	Substantially equivalent *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	Identical
Patient contacting tubing material	Polyurethane	Polyurethane	Identical
Biocompatibility	ISO 10993	FDA application of ISO 10993	Substantially Equivalent
Feeding Connector	80369-3 Connector - ENFit	80369-3 Connector - ENFit	Identical
Sterilization	Non-sterile	Non-sterile	Identical
Target User	Intended for use by physicians, technicians and nutritionists.	Intended for use by physicians, technicians and nutritionists.	Identical
Use Environment	Hospitals and other healthcare facilities	Hospitals and other healthcare facilities	Identical
Access / Anatomical Site	Nasoenteric	Oro / Nasoenteric	Substantially Equivalent
Energy Type	Electromagnetic Field	Electromagnetic Field	Identical
Patient Population	Adults	Adults	Identical

* Note: Indications for Use statement for K821906 are not currently available.

The 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:

- Corpak CORTRAK Enteral Access Device (K080679)
- Corpak CORTRAK CORFLO feeding tube (K821906)

CONCLUSION

The ENvizion Medical ENvue and Enteral Feeding Tube are substantially equivalent to the CORTRAK Enteral Access Device and CORTRAK CORFLO NasoEnteric Feeding Tube with Transmitting Stylet.