December 10, 2019

Health Line International Corporation
Joel Faulkner
CEO
5675 W 300 S
Salt Lake City, Utah 84117

Re: K192533
Trade/Device Name: Health Line CT CVC
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: September 12, 2019
Received: September 16, 2019

Dear Joel Faulkner:

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 Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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)*
K192533

Device Name
Health Line CT CVC

Indications for Use *(Describe)*
The HEALTH LINE CT CVC is indicated for short term (less than 30 days) access to the central venous system for intravenous administration of fluids, medications, blood products, and/or nutritional therapy solutions when prescribed. Blood sampling and power injection of contrast media may also be conducted with the HEALTH LINE CT CVC.

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
(As required by 21 CFR 807.92)

SUBMITTER:
Health Line International Corporation
5675 West 300 South
Salt Lake City, Utah 84104

ESTABLISHMENT REGISTRATION NUMBER:
3006097687

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DATE PREPARED:
November 20, 2019

NAME OF MEDICAL DEVICE:

Proprietary Name:	***Health Line CT CVC***
Regulation Name:	Intravascular Catheter
Common/Usual Name:	Central Venous Catheter (CVC), single, double and triple lumen, short-term less than 30 days

DEVICE CLASSIFICATION:

Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	FOZ
Regulation Number:	21 CFR 880.5200

PREDICATE DEVICE:

Proprietary Name:	***Orion™ II CT CVC*** (K113622)
Regulation Name:	Intravascular Catheter
Common/Usual Name:	Central Venous Catheter (CVC), single, double and triple lumen, short-term less than 30 days
Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	FOZ
Regulation Number:	21 CFR 880.5200

DEVICE DESCRIPTION:

The *HEALTH LINE CT CVC* is a family of central venous catheters designed to perform infusion, intravenous therapy, blood sampling and also power injection of contrast media studies. The catheters, made of radiopaque polyurethane tubing, are inserted in a central vein. Each *HEALTH LINE CT CVC* has a kink resistant, gradual tapered catheter design. The *HEALTH LINE CT CVC* kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The *HEALTH LINE CT CVC* is indicated for dwell times shorter than 30 days. The *HEALTH LINE CT CVC* catheter assemblies have been tested to withstand power injection of worst-case viscosity injection media at 5 ml/sec with a maximum power injector pressure of 300 psi.

The *HEALTH LINE CT CVC* product line has catheters in 16 G and 14 G single lumen, 5 Fr and 7 Fr dual lumen and 7 Fr triple lumen. Catheters range from approximately 13-30 cm long. The catheters are attached to an injection-molded polyurethane hub that has extension legs with Luer lock fittings for access attachment. All HEALTH LINE CT CVC products have a maximum recommended infusion rating is 5 ml/sec. The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.

INDICATIONS FOR USE:

The *HEALTH LINE CT CVC* is indicated for short term (less than 30 days) access to the central venous system for intravenous administration of fluids, medications, blood products, and/or nutritional therapy solutions when prescribed. Blood sampling and power injection of contrast media may also be conducted with the *HEALTH LINE CT CVC*.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICE:

The *HEALTH LINE CT CVC* is IDENTICAL to the predicate device the Orion™ II CT CVC (K113622) in ALL aspects except:

- New labeling, Instructions for use (IFU) (with additional instructions), addition suture wing components (to provide clinicians with additional options, if desired) in the kit configuration.
- Catheter length – Exactly same as predicate.
- Insertion site – Exactly the same as predicate Orion™ II CT CVC and is placed in a central vein.
- Dwell time – Exactly the same as predicate Orion™ II CVC is indicated for short term access.

The changes do not impact the performance or safety and effectiveness of the device compared to the predicate.

The *HEALTH LINE CT CVC* subject device and the predicate device Orion™ II CT CVC (K113622) are manufactured by the same company, Health Line International Corporation, the submitter of this submission.

Comparison Area	***Submission Device HEALTH LINE CT CVC***	***Predicate Device Orion™ II CT CVC*** K113622
Indications for Use:	The Health Line CT CVC is indicated for short term (less than 30 days) access to the central venous system for intravenous administration of fluids, medications, blood products, and/or nutritional therapy solutions when prescribed. Blood sampling and power injection of contrast media may also be conducted with the Health Line CT CVC.	The Orion™ II CT CVC is indicated for short term (less than 30 days) access to the central venous system for intravenous administration of fluids, medications, blood products, and/or nutritional therapy solutions when prescribed. Blood sampling and power injection of contrast media may also be conducted with the Orion™ II CT CVC. **Different- Updated with name of catheter**
Intended Use:	Intended to be used by medical professionals for short term access to the central venous system for infusion, intravenous therapy, blood sampling and power injection of contrast media	Identical
Target Population	Adults	Identical
Duration of Use	Less than 30 days	Identical
Insertion Method	Seldinger Technique	Identical
Tip Placement Location	Located just before the junction of the superior vena cava and the right atrium	Identical
Insertion Site	Inserted percutaneously and primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian vein.	Identical
Sizes	16G & 14G Single Lumen, 5 & 7 Fr Dual Lumen and 7 Fr Triple Lumen	Identical
Labeling	New Health Line CT CVC logo	Orion™ II CT CVC logo.
Instructions for Use	Added optional use of suture wing to instructions, added priming volumes	Without suture wing instructions and priming volumes.
Components	Added suture wing securement device to kit components.	Without suture wing.
Biocompatibility	ISO-10993	Identical
Sterilization Method	EtO (SAL 10^{-6})	Identical
Materials		
Female Luer connectors	Rigid PVC	Identical
Hub	Polyurethane	Identical
Catheter Tubing	Polyurethane	Identical

Extension Leg Tubing	Polyurethane	Identical
Pinch Clamps	Acetal	Identical
Informational Clamp Inserts	ABS	Identical

PERFORMANCE TESTING

The subject device is identical to the predicate device (K113622) in its final finished form. Therefore, the biocompatibility and performance data were leveraged from the predicate device. The subject device complies with FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95.

The subject device complies with sterilization requirements of ISO 11135-1:2007, *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.* It also complies with AAMI TIR 28, *Product adoption and process equivalence for ethylene oxide sterilization.*

CONCLUSION

Based on the Indications for Use, technological characteristics and performance testing; the ***HEALTH LINE CT CVC*** is substantially equivalent to the following predicate device *Orion™ II CT CVC (K113622).*