March 12, 2020

Health Line International Corporation
Aaron Faulkner
RA Director
5675 W 300 S
Salt Lake City, Utah 84104

Re: K200263
Trade/Device Name: Health Line CT Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: January 6, 2020
Received: February 3, 2020

Dear Aaron 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)*
K200263

Device Name
Health Line CT Midline Catheter

Indications for Use *(Describe)*
The HEALTH LINE CT MIDLINE CATHETER is indicated for short term (less than 30 days) access to the peripheral venous system for infusion, intravenous therapy and blood sampling. The HEALTH LINE CT MIDLINE CATHETER is suitable for use with power injectors.

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 OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for *HEALTH LINE CT MIDLINE CATHETER*
(K200263)

SUBMITTER:
Health Line International Corporation
5675 W 300 S
Salt Lake City, Utah 84104

ESTABLISHMENT REGISTRATION NUMBER:
3010882065

CONTACT:
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Director Engineering
Telephone: 801-773-7798
Fax: 855-228-1336
Email: agfaulkner@hlic.net

DATE PREPARED:
December 20, 2019

NAME OF MEDICAL DEVICE:

Proprietary Name:	***HEALTH LINE CT MIDLINE CATHETER (K200263)***
Regulation Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Common/Usual Name:	Midline Catheter, single and double lumen

DEVICE CLASSIFICATION:

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

PREDICATE DEVICE:

Proprietary Name:	***NEXUS MIDLINE CT (K140270)***
Regulation Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Common/Usual Name:	Midline Catheter, single and double lumen

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

DEVICE DESCRIPTION:

The HEALTH LINE CT MIDLINE CATHETER is a family of peripherally inserted peripheral catheters made from specially formulated biocompatible medical grade materials. Catheters are packaged in a tray with accessories necessary for a percutaneous micro introducer introduction (Modified Seldinger or Seldinger technique). The device is intended for short term (less than 30days) vascular access.

The HEALTH LINE CT MIDLINE CATHETER is indicated for dwell times shorter than 30 days. The HEALTH LINE CT MIDLINE CATHETER product line will have catheters in 3Fr, 4 Fr and 5 Fr single lumen, and 4 Fr and 5 Fr dual lumen. The HEALTH LINE CT MIDLINE CATHETER's are supplied in two lengths, approximately 10 and 20 cm long. All catheters are attached to an injection-molded polyurethane hub that has extension legs with Luer lock fittings for access attachment.

Catheter Size	Priming Volume (ml)	Max Flow Rate (ml/sec)*	Max Internal Catheter Pressure at Max Flow Rate (psi)	Rated Burst Pressure (psi)**
3Fr Single Lumen	0.29	1	167	251
4Fr Single Lumen	0.37	5	164	299
4Fr Dual Lumen	0.35/0.35	3	173/173	299
5Fr Single Lumen	0.38	5	112	300
5 Fr Dual Lumen	0.37/0.37	5	179/179	299
*Pressurized flow rates are determined with pump safety cut-off at 300 psi using viscous fluid at 11.8 centipoise (cP) and represents approximate flow capability of power injection of contrast media ** Max Burst Pressure is the static burst pressure failure point of the catheter when the lumen is completely occluded. **WARNING**: Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.				

INTENDED USE

The HEALTH LINE CT MIDLINE CATHETER is intended to be used by medical professionals for short term percutaneous access to the peripheral venous system for infusion, intravenous therapy and for blood sampling.

INDICATIONS FOR USE:

The HEALTH LINE CT MIDLINE CATHETER is indicated for short term (less than 30 days) access to the peripheral venous system for infusion, intravenous therapy and blood sampling. The HEALTH LINE CT MIDLINE CATHETER is suitable for use with power injectors.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

The HEALTH LINE CT MIDLINE CATHETER is technologically identical to the, NEXUS MIDLINE CT CATHETER (K140270), predicate device in all aspects. The Health Line CT Midline Catheter is identical to the predicate device in all aspects except for: a name change, priming instructions added to the instructions for use, and a catheter trim tool was added to the device kit.
Below is a summary table comparing the HEALTH LINE CT MIDLINE Catheter to the predicate NEXUS MIDLINE CT CATHETER (K140270).

Summary of Technological Comparison of Subject Device to Predicate Devices

<table>
<tr><th>Technological Comparison Area</th><th>Subject Device
HEALTH LINE CT MIDLINE CATHETER
(K200263)</th><th>Predicate Device
Nexus Midline CT Catheter
(K140270)</th></tr>
<tr><td>Indications for Use:</td><td>The HEALTH LINE CT MIDLINE CATHETER is indicated for short term (less than 30 days) access to the peripheral venous system for infusion, intravenous therapy and blood sampling. The HEALTH LINE CT MIDLINE CATHETER is suitable for use with power injectors.</td><td>The NEXUS™ MIDLINE CT CATHETER is indicated for short term (less than 30 days) peripheral access to the peripheral venous system for infusion, intravenous therapy and blood sampling. The NEXUS™ MIDLINE CT CATHETER is suitable for use with power injectors. For maximum flow rate and maximum pressure that can be used during power injection, please refer to the following:
<table>
<tr><th>Catheter Size</th><th>Priming Volume (ml)</th><th>Max Labeled Flow Rate (ml/sec)*</th><th>Max Internal Catheter Pressure at Max Flow Rate (psi)</th><th>Rated Burst Pressure (psi)**</th></tr>
<tr><td>3Fr Single Lumen</td><td>0.29</td><td>1</td><td>167</td><td>251</td></tr>
<tr><td>4Fr Single Lumen</td><td>0.37</td><td>5</td><td>164</td><td>299</td></tr>
<tr><td>4Fr Dual Lumen</td><td>0.35/0.35</td><td>3</td><td>173/173</td><td>299</td></tr>
<tr><td>5Fr Single Lumen</td><td>0.38</td><td>5</td><td>112</td><td>300</td></tr>
<tr><td>5 Fr Dual Lumen</td><td>0.37/0.37</td><td>5</td><td>179/179</td><td>299</td></tr>
</table>
* Pressurized flow rates are determined with pump safety cut-off at 300 psi using viscous fluid at 11.8 centipoise (cP) and represents approximate flow capability of power injection of contrast media.
* * Max Burst Pressure is the static burst pressure failure point of the catheter when the lumen is completely occluded. WARNING: Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.</td></tr>
<tr><td>Intended Use:</td><td>Intended to be used by medical professionals for short term peripheral access to the venous system for infusion, intravenous therapy, blood sampling and power injection of contrast media.</td><td>Identical</td></tr>
<tr><td>Target Population</td><td>Adults</td><td>Identical</td></tr>
<tr><td>Duration of Use</td><td>Less than 30 days</td><td>Identical</td></tr>
<tr><td>Insertion Method</td><td>Seldinger Technique</td><td>Identical</td></tr>
<tr><td>Sizes</td><td>3Fr, 4Fr, 5Fr Single Lumen, 4Fr & 5Fr Dual Lumen</td><td>Identical</td></tr>
<tr><td>Biocompatibility</td><td>ISO-10993</td><td>Identical</td></tr>
<tr><td>Sterilization Method</td><td>EtO (SAL 10^{-6})</td><td>Identical</td></tr>
<tr><td colspan="3">Materials</td></tr>
<tr><td>Female Luer connectors</td><td>Rigid PVC</td><td>Identical</td></tr>
<tr><td>Hub</td><td>Polyurethane</td><td>Identical</td></tr>
<tr><td>Catheter Tubing</td><td>Polyurethane</td><td>Identical</td></tr>
</table>

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 (K140270) 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.*

A risk analysis was performed with respect to these changes and no risks were identified with these changes.

CONCLUSION

Based on FDA's decision tree the ***HEALTH LINE CT MIDLINE CATHETER*** is substantially equivalent to the, Nexus Midline CT Catheter (K140270), predicate device.