March 9, 2020

Health Line International Corporation
John Lincoln
Principal Consultant
Po Box 2786
St. George, Utah 84771-2786

Re: K140270
Trade/Device Name: Nexus Midline Ct Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: January 30, 2014
Received: February 3, 2014

Dear John Lincoln:

This letter corrects our substantially equivalent letter of August 20, 2014.

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,

Sapana Patel -S

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)*
K140270

Device Name
Nexus™ Midline CT Catheter

Indications for Use *(Describe)*
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:

Catheter Size	Priming Volume (ml)	Max Labeled 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.

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 OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for *NEXUS™ MIDLINE CT CATHETER*

SUBMITTER:
Health Line International Corporation
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Centerville, Utah 84014

ESTABLISHMENT REGISTRATION NUMBER:
3006097687

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DATE PREPARED:
January 30, 2014

NAME OF MEDICAL DEVICE:

Proprietary Name:	***NEXUS™ MIDLINE CT CATHETER***
Regulation Name:	Intravascular Catheter
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 DEVICES:

Proprietary Name:	***SYNERGY™ CT PICC (K101329)***
Regulation Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC), single, double and triple lumen
Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	L J S
Regulation Number:	21 CFR 880.5970

Proprietary Name:	***UNI-PICC™ (K130034)***
Regulation Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC), single, double and triple lumen
Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	L J S
Regulation Number:	21 CFR 880.5970

Proprietary Name:	***Vascu-PICC® and Midline Catheters, Single, Double and Triple Lumen (K091586)***
Regulation Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
Common/Usual Name:	Catheter, Intravascular, Therapeutic, Long-Term
Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	L J S
Regulation Number:	21 CFR 880.5970

Proprietary Name:	***PowerGlide Midline Catheter (K121073)***
Regulation Name:	Intravascular Catheter
Common/Usual Name:	Intravascular Catheter
Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	FOZ
Regulation Number:	21 CFR 880.5200

DEVICE DESCRIPTION:

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

The NEXUS™ MIDLINE CT Catheter is indicated for dwell times shorter than 30 days. The NEXUS™ MIDLINE CT Catheter product line will have catheters in 3Fr, 4 Fr and 5 Fr single lumen, and 4 Fr and 5 Fr dual lumen. The NEXUS™ MIDLINE CT Catheters 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.

INTENDED USE:

The *NEXUS™ MIDLINE CT Catheter* is intended to be used by medical professionals for short-term percutaneous access to the venous system for infusion, intravenous therapy and for blood sampling.

The intended use for the *NEXUS™ MIDLINE CT Catheter* has not changed from that of the *SYNERGY™ CT PICC (K101329)* and *UNI-PICC™* (K130034) predicate devices.

INDICATIONS FOR USE:

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:

Catheter Size	Priming Volume (ml)	Max Labeled 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
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* 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.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New device is compared to Marketed Device? Yes. It is compared to four legally marketed predicate devices.

Does the new device have the same indication statements? Yes the indications for use statement is basically the same as the *SYNERGY™ CT PICC (K101329)* and the *UNI-PICC™ (K130034)* predicate devices.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e., deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended effect of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Yes. The device of this submission, the *NEXUS™ MIDLINE CT CATHETER*, is identical to that of the predicate devices. In fact, the *SYNERGY™ CT PICC* and the *UNI-PICC™* are manufactured by the same company, Health Line International Corporation, the submitter of this submission. The basic fundamental scientific technology of the device has not changed. There may be minor variations in the contents of the introduction kit components.

Could the new characteristics affect safety or effectiveness? No.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95 was used to determine the appropriate methods for evaluating the device's performance.

Sterilization requirements of ISO 11135:2007, *Sterilization of Health Care Products - Requirements for Validation and Routine Control -- Ethylene Oxide Sterilization.*

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*. Test profiles for externally communicating, blood-contacting, long-term devices will be met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Nonclinical tests submitted included appropriate biocompatibility tests, as well as performance bench testing. Bench test data including Tensile Strength Test, Power Injection Performance Test, Dynamic Failure Test, Static Pressure Test, Static Burst Test, Life Cycle Power Injection Test, Catheter Flow Rate Test, Air Leakage Test and Liquid Leakage Test all met predefined acceptance criteria, and supported the substantial equivalence determination.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrated that the *NEXUS™ MIDLINE CT Catheter* is substantially equivalent to the noted predicate devices.

CONCLUSION

The ***NEXUS™ MIDLINE CT Catheter*** met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the ***NEXUS™ MIDLINE CT Catheter*** is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the *SYNERGY™ CT PICC* (K101329), *UNI-PICC™ (K130034), Vascu-PICC® and Midline Catheters, Single, Double and Triple Lumen* (K091586) and *PowerGlide Midline Catheter* (K121073).