DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 12, 2016

Health Line International Corporation
Mr. Joel K. Faulkner
CEO
5675 West 300 South
Salt Lake City, UT 84101

Re: K160448
Trade/Device Name: ARTLINE
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQX
Dated: June 6, 2016
Received: June 8, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Pullin -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160448

Device Name
ARTLINE

Indications for Use *(Describe)*
The ARTLINE Device is intended to permit access to the peripheral arterial circulation system for short term access (less than 30 days).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
(21 CFR 807.92)
for *ARTLINE*

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

ESTABLISHMENT REGISTRATION NUMBER:
3006097687

CONTACT:
Joel K. Faulkner
Telephone: 801-773-7798
Fax: 801-820-8007
Email: jkfaulkner@hlic.net

DATE PREPARED:
February 8, 2016

NAME OF MEDICAL DEVICE:

Proprietary Name:	***ARTLINE***
Regulation Name:	Catheter Guide Wire / Percutaneous Catheter
Common/Usual Name:	Catheter Guide Wire / Percutaneous Catheter

DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DQX / DQY
Regulation Number:	21 CFR 870.1330

PREDICATE DEVICES:

Proprietary Name:	***ARROW RADIAL ARTERY CATHETERIZATION SET***
Regulation Name:	Wire, Guide, Catheter
Common/Usual Name:	Catheter Guide Wire
Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DQX
Regulation Number:	21 CFR 870.1330

Proprietary Name: ***N/A***

DEVICE DESCRIPTION:

The ARTLINE is a single lumen peripherally inserted catheter device designed to perform short term access to the peripheral arterial circulatory system for less than 30 days. The catheter, made of radiopaque polyurethane tubing, echogenic needle, guidewire with slide advancer. Each ARTLINE has a kink resistant catheter design. The catheter is inserted over the needle into the peripheral arterial vessel, the guide wire is advanced and the catheter is threaded over the guide wire. The catheter is supplied sterile and non-pyrogenic.

The ARTLINE is indicated for dwell times shorter than 30 days. The ARTLINE is a 20ga single lumen catheter. The catheter is approximately 4.45 cm long. The catheters are attached to an injection-molded polyurethane hub with Luer lock fittings for access attachment.

INTENDED USE:

The ARTLINE Device is intended to permit access to the peripheral arterial circulation system for short term access (less than 30 days).

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

The ARTLINE catheter uses the same fundamental technology as the predicate device.

Substantial Equivalence Comparison		
Comparison Criteria	Subject Device: Health Line, ARTLINE Catheter	Predicate Device: ARROW INTL. Radial Artery Catheter (K810675)
Same Intended Use	Yes	Yes
Prescription Device (Rx Only)	Yes	Yes
Biocompatible Polyurethane Catheter	Yes	Yes
Biocompatible Materials of Fabrication	Yes	Yes
Design	Yes	Yes
Intended Anatomical Location	Yes, Peripheral Arterial Vasculature	Yes, Peripheral Arterial Vasculature
EO Sterilization Method	Yes	Yes
Packaged Sterile, Single Use	Yes	Yes
Non-Pyrogenic	Yes	Yes
Made without Latex Rubber	Yes	Yes
Made without DEHP	Yes	Yes

Performance Tests:

- Air Leakage
- Liquid Leakage
- Tensile Strength Test
- Catheter Flow Rate
- Priming Volume
- Chemical Test
- 6% Conical Fitting
    - Liquid Leakage
    - Air Leakage
    - Separation Force
    - Unscrewing Force
    - Ease of Assembly
    - Resistance to Override
    - Stress Cracking
- Needle Penetration Test
- Kink Test

CONCLUSION

The ***ARTLINE*** met all established acceptance criteria for performance testing and design verification testing. The performance testing demonstrated that the ARTLINE is substantially equivalent to the predicate device, ARROW RADIAL ARTERY CATHETERIZATION (K810675), in safety and performance.