MAY - 4 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for *HLIC NEEDLE-LESS VALVE*

SUBMITTER:
Health Line International Corporation
803 N. 1250 W. – STE 1
Centerville, Utah 84014

ESTABLISHMENT REGISTRATION NUMBER:
3006097687

CONTACT:
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DATE PREPARED:
February 21, 2012

NAME OF MEDICAL DEVICE:

Proprietary Name:	***HLIC NEEDLE-LESS VALVE***
Regulation Name:	Intravascular Administration Set
Common/Usual Name:	Needle Free Injection Site

DEVICE CLASSIFICATION:

Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	FPA
Regulation Number:	21 CFR 880.5440

PREDICATE DEVICE:

Proprietary Name:	Swabsite Swabbable Valve
Regulation Name:	Intravascular Administration Set
Common/Usual Name:	Intravascular Administration Set / Swabbable Valve
Classification Panel:	General Hospital
Regulator Class:	Class II
Product Code:	FPA
Regulation Number:	21 CFR 880.5440

DEVICE DESCRIPTION:

The HLIC Needle-Less Valve is a needle free valve that allows the user to add medication into IV sets without the use of a needle. When the valve is in the closed position, it has a flat, smooth surface for cleaning. When the male connector of a syringe or secondary line is pushed into the valve, the silicone stem opens in the middle creating a fluid path. When the male connector is removed from the valve, the body of the valve forces the stem shut and maintains a sealed fluid path. A cap is not required to seal the valve or to maintain sterility.

INTENDED USE:

The HLIC Needle-Less Valve is intended to allow access to IV administration sets, medication vials, blood donor collection bags, and solution bags with one convenient device without the use of needles or blunt cannulas.

INDICATIONS FOR USE:

The HLIC Needle-Less Valve is intended to allow access to IV administration sets, medication vials, blood donor collection bags, and solution bags with one convenient device without the use of needles or blunt cannulas.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New device is compared to Marketed Device? Yes. It is compared to legally marketed predicates.

Does the new device have the same indication statements? Yes.

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 use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Yes. The *HLIC NEEDLE-LESS VALVE*, is substantially equivalent to the Swabsite Swabbable Valve *K002689*. The basic fundamental scientific technology of the device has not changed.

Could the new characteristics affect safety or effectiveness? No.

Do the new characteristics raise new types of safety and effectiveness questions? No. The only new characteristic is that the *HLIC NEEDLE-LESS VALVE* is power injection capable. This is based upon existing test data and does not affect safety or effectiveness.

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

Power Injection testing was conducted to assess the power injection capabilities of the HLIC NEEDLE-LESS VALVE.

Biocompatibility requirements according to ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*. Test profiles for externally communicating, Blood path, indirect, Limited contact duration (<24 hours) were 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.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrated that the ***HLIC NEEDLE-LESS VALVE*** is substantially equivalent to the noted predicate devices.

CONCLUSION

The ***HLIC NEEDLE-LESS VALVE*** met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the ***HLIC NEEDLE-LESS VALVE*** is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate device: *Swabsite Swabbable Valve (K002689).*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Nola Benstog
Director QA/RA
Health Line International Corporation
803 North 1250 West, Suite 1
Centerville, Utah 84014

MAY - 4 2012

Re: K120548
Trade/Device Name: HLIC NEEDLE-LESS VALVE
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: April 26, 2012
Received: April 27, 2012

Dear Ms. Benstog:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K120548

Device Name: ***HLIC NEEDLE-LESS VALVE***

Indications For Use:

The HLIC Needle-Less Valve is intended to allow access to IV administration sets, medication vials, blood donor collection bags, and solution bags with one convenient device without the use of needles or blunt cannulas.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RLC Chen 5/4/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120548