



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 21, 2015

Nostix LLC
c/o Mr. Jim Lewis
Salus Ventures LLC
5335 Holmes Place
Boulder, Colorado, 80303

Re: K152261

Trade/Device Name: PICC Tip Positioning Aid
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: August 7, 2015
Received: August 11, 2015

Dear Mr. Lewis:

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" (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 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,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152261

Device Name

PICC Tip Positioning Aid

Indications for Use (Describe)

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

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

Prepared: 25 September 2015

Submitter

Company	Nostix LLC 5541 Central Av, Suite 170 Boulder, CO 80301
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Device

Trade Name	PICC Tip Positioning Aid
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Predicate

Trade Name	Celerity System
Clearance	K142889, 27 January 2015
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Device Description

The PICC Tip Positioning Aid includes a standalone Monitor containing software, battery and power cord accompanied by an ECG Patient Cable, a Remote Control Cable, probe cover and ECG Clip Cable.

Other procedural accessories; including ECG Snap Leads, ECG Surface Electrodes, Cable Cover, Gloves and Prep Pads; may be provided as a convenience for the clinician but are not in the scope of this submission.

Intended Use

The PICC Tip Positioning Aid is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Indications for Use

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

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- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Technological Characteristics

Technological Characteristics of the subject PICC Tip Positioning Aid are identical to the predicate device. The name and address changes on the labels between the predicate and proposed devices do not raise new technological questions.

Performance Data

As the only differences between the device and its predicate are names, logos, and addresses in the labeling, the following recognized standards from the IEC 60601 (3rd Edition) series continue to be satisfied.

IEC 60601-1-1 Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems

IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility – Requirements and tests

Human Factors Evaluation - Simulated Use Testing alternate to chest x-ray and fluoroscopy: Simulated Use / Human Factors Testing has been conducted to evaluate the application of the PICC Tip Placement Aid as embodied in the predicate Celerity System when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. The use related events noted in the studies have been adequately reviewed and addressed in order to ensure the appropriate use of the device as an alternate to x-ray techniques for confirmation of tip location of PICC.

Based on the content of the proposed PICC Tip Positioning Aid's Risk Analysis / Use and Design FMEAs, and the content of the Instructions for Use, the PICC Tip Positioning Aid has demonstrated its suitability for its intended purpose.

Substantial Equivalence Conclusion

As this device design and manufacturing are the same as the predicate except for name changes to the device and the manufacturer, the device is clearly equivalent to its predicate.

The proposed device is clearly substantially equivalent to the predicate device based on identical:

- Intended Use
- Indications for Use
- Design
- Production
- Operating principles, characteristics, and user interface
- Technology and specifications
- Labeling