May 27, 2020

Philips Medical Systems Nederland B.V.
Gert De Vries
Senior Regulatory Affairs Manager
Veenpluis 4-6
Best, 5684 PC Nl

Re: K192914
Trade/Device Name: Stimuplex Onvision System
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP, IYO
Dated: April 24, 2020
Received: April 27, 2020

Dear Gert De Vries:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K192914

Device Name
Stimuplex Onvision system

Indications for Use *(Describe)*

The Stimuplex® Onvision® system is intended for clinically trained physicians to perform regional anesthesia and pain therapy to target peripheral nerves by tracking the B.Braun Stimuplex® Onvision® needle tip position by overlaying a circle at the given location using the Philips Xperius® Ultrasound and Onvision® System. The B.Braun Stimuplex® Onvision® needle is used to inject local anesthesia or analgesic to the targeted nerve bundle to induce regional anesthesia for surgical procedures. The Stimuplex® HNS 12 can also be used for nerve stimulation when connected to the system cable.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

### SUBMITTER INFORMATION:


| | |
|---|---|
| **Name:** | Philips Medical Systems B.V. |
| | Philips Image Guided Therapy – Business Incubation |
| **Address:** | Building QG-132, Veenpluis 4-6, 5684 PC Best, |
| | The Netherlands |
| **Telephone Number:** | +31 (0)6 182 06 281 |
| **Contact Person:** | Gert de Vries, Senior Regulatory Affairs Manager |
| **Telephone Number:** | +31 (0)6 182 06 281 |
| **Email:** | gert.de.vries@philips.com |
| **Date Prepared:** | April 23rd, 2020 |


### DEVICE NAME:

| | |
|---|---|
| Device Trade Name: | Stimuplex® Onvision® system |
| Common Name: | Anesthesia Conduction Needle with Ultrasonic Tip Tracking System |
| Classification Name: | Anesthesia conduction needle 21 CFR §868.5150: Class II, Product code BSP and System, Imaging, Pulsed Echo, Ultrasonic 21 CFR §892.1560, Class II Product code IYO |

### PREDICATE DEVICES:

- Primary predicate device: SonixGPS Nerve Block Needle Kit, Ultrasonix Medical Corporation (K121812)
- Additional predicate devices:
  - PercuNav Image Fusion and Interventional Navigation (K170716)
  - B.Braun Stimuplex® D Plus Insulated Echogenic Needle(K100241)

### DEVICE DESCRIPTION:

The proposed Stimuplex® Onvision® system is an add-on device to the Philips Xperius ultrasound system (K182529) that is intended to be used during peripheral nerve block (PNB) procedures. The proposed Stimuplex® Onvision® system consists of:

- a dedicated sterile, single-use Stimuplex® Onvision® needle(manufactured by B. Braun)
- Onvision system (manufactured by Philips) which contains:
  - a non-sterile reusable hardware with battery,
  - needle tip tracking software
  - and a system cable.

The Stimuplex Onvision system is also compatible with the Stimuplex HNS 12 nerve stimulator( K070134).

**INDICATIONS FOR USE:**

The Stimuplex® Onvision® System is intended for clinically trained physicians to perform regional anesthesia and pain therapy to target peripheral nerves by tracking the B.Braun Stimuplex® Onvision® needle tip position by overlaying a circle at the given location using the Philips Xperius® Ultrasound and Onvision® System. The B.Braun Stimuplex® Onvision® needle is used to inject local anesthesia or analgesic to the targeted nerve bundle to induce regional anesthesia for surgical procedures. The Stimuplex® HNS 12 can also be used for nerve stimulation when connected to the system cable.

**TECHNOLOGICAL CHARACTERISTICS:**

The Stimuplex® Onvision® system has the same intended use as the primary predicate device of SonixGPS Nerve Block Needle kit (K121812), and an additional predicate device of Stimuplex D Plus Insulated Echogenic Needle(K100241). It also has the same intended use as another additional predicate device of PercuNav Image Fusion and Interventional Navigation (K170716) for the purpose of use during PNB procedures (nerve block and pain management). The predicate device of PercuNav has wider scope of intended use in other procedures.

Both proposed device and primary predicate device of SonixGPS needle kit:

- contain a needle to inject a single dose of anesthetic or analgesic for the purpose of regional anesthesia and pain management during PNB procedures
- contain a tracking technology to calculate the position of needle tip and display the position on live ultrasound image

For the tracking technology, the proposed device and the primary predicate device and an additional predicate device of PercuNav:

- use of an external energy field [ultrasound (acoustic) *vs* electromagnetic] for tracking
- use the ultrasound transducer for image processing
- overlay/fuse image of tracked instrument / needle with live ultrasound image
- calculate location of the tracked instrument / needle in 3D and visualization in 2D ultrasound image

- use real-time visualization of Ultrasound during interventional procedure

The proposed Stimuplex Onvision needle has fundamentally the same materials of composition as the additional predicate device of Stimuplex D Plus needle, and both the proposed and predicate devices are covered and insulated needles.

There is technological difference between the proposed and predicate devices. Stimuplex® Onvision® system uses ultrasound (acoustic) low energy field while SonixGPS needle and PercuNav employs electromagnetic energy field for tracking the needle. They are all using an external low energy field. The proposed Stimuplex® Onvision® System, SonixGPS needle and PercuNav calculate the positional information of tracked instrument/needle by utilizing the signal converted from external energy field, and overlay/fuse the image of tracked instrument/needle with ultrasound image.

The technological difference does not raise any new questions regarding safety and effectiveness, with the assessment performed in multiple aspects, including electrical safety, EMC evaluation, thermal effect etc.

Based on the information provided above, the Stimuplex Onvision system is considered substantially equivalent to the predicate devices, SonixGPS Nerve Block Needle Kit, PercuNav and Stimuplex D Plus needle, from a technical characteristics perspective.

| Item | Proposed Stimuplex® Onvision® System | Primary Predicate Device SonixGPS Nerve Block Needle Kit (K121812) | Predicate Device PercuNav Image Fusion and Interventional Navigation (K170716) | Predicate Device B.Braun Stimuplex® D Plus Insulated Echogenic Needle (K100241) | Analysis and conclusion |
|---|---|---|---|---|---|
| Indications for Use | The Stimuplex® Onvision® System is intended for clinically trained physicians to perform regional anesthesia and pain therapy to target peripheral nerves by tracking the B.Braun Stimuplex® Onvision® needle tip position by overlaying a circle at the given location using the Philips Xperius® Ultrasound and Onvision® System. The B. Braun Stimuplex® Onvision® needle is used to inject local anesthesia or analgesic to the targeted nerve bundle to induce regional anesthesia for surgical procedures. The Stimuplex® HNS 12 can also be used for nerve stimulation when connected to the system cable. | The SonixGPS Nerve Black Needle Kit is intended for use in regional anesthesia and pain therapy by a trained physician, to target peripheral nerves by visualization at the needle tip using an ultrasound imaging device. The needle is used to inject local anesthesia or analgesic to the targeted nerve bundle to induce regional anesthesia for surgical procedures. | The PercuNav system is a stereotaxic accessory for computed tomography (CT), magnetic resonance (MR), ultrasound (US), and positron emission tomography (PET). CT, Ultrasound, PET, and MR may be fused in various combinations, such as CT with MR, MR with ultrasound, and so on. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument. The PercuNav system is intended for treatment planning and guidance for clinical, interventional, or diagnostic procedures. The PercuNav system also supports an image-free mode in which the proximity of the interventional device is displayed relative to | The B. Braun Stimuplex® D Plus Insulated Echogenic Needle is intended for use in regional anesthesia and pain therapy to target peripheral nerves by transferring electrical impulses from a nerve stimulator and for visualization of an echogenic reflective pattern at the needle tip using an ultrasound imaging device. The needle is used to inject a single dose of local anesthetic or analgesic to the targeted nerve bundle for general and orthopedic surgery. | Both devices utilize ultrasound and electrical nerve stimulation for nerve detection while performing Peripheral Nerve Blocks. Both devices are used to inject a single dose of anesthetic or analgesic. The proposed device is exclusively for the Philips Onvision system. |

| Item | Proposed Stimuplex® Onvision® System | Primary Predicate Device SonixGPS Nerve Block Needle Kit (K121812) | Predicate Device PercuNav Image Fusion and Interventional Navigation (K170716) | Predicate Device B.Braun Stimuplex® D Plus Insulated Echogenic Needle (K100241) | Analysis and conclusion |
|---|---|---|---|---|---|
| | | | another device. The PercuNav system is intended to be used in interventional and diagnostic procedures in a clinical setting. The PercuNav system is also intended for use in clinical interventions to determine the proximity of one device relative to another. Example procedures include, but are not limited to, the following:<br>• Image fusion for diagnostic clinical examinations and procedures<br>• Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, and so on.)<br>• Soft tissue ablation (liver, kidney, breast, pancreas, lung, and so on)<br>• Bone ablations<br>• Bone biopsies<br>• Nerve blocks and pain management<br>• Drainage placements<br>• Tumor resections | | |
| Intended Use | Regional anesthesia and Pain Therapy | Regional anesthesia and Pain Therapy | Nerve blocks and pain management<br>See part of indication of use | Regional anesthesia and Peripheral Nerve Blocks | The Intended Use is the same. However, the Intended Use for PercuNav is broader |
| Classification | Class II | Class II | Class II | Class II | Same |
| Product Code | BSP,IYO | BSP | IYO,LLZ | BSP | Same, combination of the two predicates |
| Ultrasound Visibility | Shaft identification and needle tip tracking in ultrasound image when connected to Philips Onvision System | Shaft identification and visualization at the needle tip using an ultrasound imaging device | Shaft identification and visualization at the needle tip using an ultrasound imaging device | Needle tip and shaft identification in an ultrasound image | Same |
| Biocompatibility classification | External communicating device bone/tissue/dentin limited exposure | Information is not publically available | N/A | External communicating device bone/ tissue/dentin limited exposure | Same |
| Needle tube | Stainless steel | Information is not publically available | see CIVCO needle information | Needle tube: Stainless steel | The materials of construction of the proposed device and the predicate devices are similar. |
| Needle Dimensions Needle Gauge / Outer diameter x Length] | 22 Ga. X 2in.<br>22 Ga. X 3 1/8in.<br>20 Ga. X 4in.<br>20 Ga. X 4 3/4in.<br>20 Ga. X 6in. | 19Ga X .55mm | Compatible with CIVCO needles | 25 Ga. x 1 3/8in.<br>22 Ga. x 2in.<br>22 Ga. x 4 3/4in. | The devices offer clinicians gauge and length options that do not affect the safety and effectiveness of the devices. |
| Sterilization | Ethylene Oxide | Ethylene Oxide | N/A | Ethylene Oxide | Same |
| Sterility Assurance Level (SAL) | $10^{-6}$ | Information is not publically available | N/A | $10^{-6}$ | Same |
| Shelf Life | 2 years | Information is not publically available | N/A | 5 years | Proposed device has a shelf life of 2 years. The shelf life does not affect the safety and effectiveness of the proposed device. |

| Item | Proposed Stimuplex® Onvision® System | Primary Predicate Device SonixGPS Nerve Block Needle Kit (K121812) | Predicate Device PercuNav Image Fusion and Interventional Navigation (K170716) | Predicate Device B.Braun Stimuplex® D Plus Insulated Echogenic Needle (K100241) | Analysis and conclusion |
|---|---|---|---|---|---|
| Stimulation ability | Yes | No | N/A | Yes | Same as Stimuplex D Plus predicate device does not affect the safety and effectiveness of the proposed device. |
| Connectivity to Nerve Stimulator | Direct | N/A | N/A | Direct | Same as Stimuplex D Plus predicate device does not affect the safety and effectiveness of the proposed device. |
| Tracking Technology | sensor in needle, sends signal back to software which calculates and displays on ultrasound screen | Sensor coil placed in needle and in transducer sends signal back to software which calculates and displays on ultrasound screen | Sensor within CNT placed in needle and in transducer sends signal back to software which calculates and displays on ultrasound screen | N/A | Equivalent, each tracking technology make use of an external energy field for tracking and displays on ultrasound screen |
| Sensor | Passive; receives energy from ultrasound probe and uses this to determine the needle tip position | Passive; receives energy from an electromagnetic source and uses this to determine the sensor position | Passive; receives energy from an electromagnetic source and uses this to determine the sensor position | N/A | Equivalent, all sensors are passive and receive energy from an external field to determine the sensor position |
| Image Modality | Live Ultrasound | Live Ultrasound | Live Ultrasound | N/A | Same |
| Sensor connection to tracking hardware | The lead wires from the sensor are connected back to the Onvision system (tracking hardware) through a cable and a unique connector to prevent connection to an incorrect socket. | The lead wires from the needle sensor are connected back to the tracking hardware though a cable and a unique connector to prevent connection to an incorrect socket. In addition the sensor within the ultrasound probe is connected to the ultrasound system. | The lead wires from the sensor are connected back to the Position Sensor unit (tracking hardware) through a cable and a unique connector to prevent connection to an incorrect socket | N/A | Same |
| Software | The software takes the calculated positional information and displays the positional information of the tracked device connected to the system. | The software takes the calculated positional information and predicted needle trajectory to display the location where the needle will intersect with the ultrasound beam and displays the positional information of the tracked device connected to the system. | The software takes the position data provided by the hardware and displays patient imaging data as well as the location and orientation of the tracked instruments connected to the system. | N/A | Equivalent. Each takes the position data and displays the positional information of the tracked device. |
| Tracked Instrumentation/ accessory | Needle tip tracking | Needle tip tracking | · Patient tracker<br>· Ultrasound tracker<br>· Coaxial needle tracker (CNT)<br>· Adaptive needle tracker (ANT)<br>· Button probes<br>· Biopsy and RFA Introducers | N/A | Same for primary predicate device, equivalent for PercuNav predicate device |
| Clinical application | Soft tissues (skin, muscle, tendon, fat etc.) | Soft tissues (skin, muscle, tendon, fat etc.) | Soft tissues (skin, muscle, tendon, fat etc.) | Soft tissues (skin, muscle, tendon, fat etc.) | Same |
| Targeted use areas | Hospitals, surgery centers, clinics: emergency room, examination room, PNB room, operating room. | Hospitals, surgery centers, clinics: emergency room, examination room, PNB room, operating room. | Hospital operating rooms, outpatient surgery centers, ultrasound, CT and other scanner suites, and procedure rooms. | Hospitals, surgery centers, clinics: emergency room, examination room, PNB room, operating room. | Same. |

**NONCLINICAL TESTING:**

Bench testing performed on Stimuplex® Onvision® system demonstrates that the device performs as intended, verifies the requirements, as well as the identified risk control measures from risk management and supports substantial equivalence of the proposed device. No clinical testing was required as substantial equivalence was demonstrated by the attributes of intended use, technological characteristics, and non-clinical testing. The following testing has been successfully completed for the proposed device:

- Single Use components (Stimuplex® Onvision® needle)
  - Biocompatibility in accordance with ISO 10993-1
    - Cytoxicity
    - Sensitization
    - Irritation/Intracutaneous reactivity
    - Material mediated Pyrogenicity
    - Acute Systemic Toxicity
    - Hemocompatibility
  - Sterilization Residual testing in accordance with ISO 10993-7
  - Sterilization Validation in accordance with ISO 11135
  - Testing in accordance with Requirements from, ISO 9626 and ISO 7864 that include:
    - Cannula stiffness
    - Tensile load
    - Resistance to breakage
  - Performance and functional testing to internal specifications that include:
    - Flowrate
    - Liquide Tightness
    - Compatibility with Philips Xperius System
    - Shelf Life Testing
- Hardware and Software components (Onvision system)
  - Electrical safety in accordance with ANSI AAMI ES 60601-1
  - EMC safety in accordance with IEC 60601-1-2
  - Software Life Cycle Processes in accordance with IEC 62304
  - Non-clinical performance testing to verify the requirements as specified in the System Requirement Specifications that include:
    - Functional requirements
    - Performance requirements
    - Service requirements
    - Physical requirements and
    - Interface requirements

Non-clinical validation testing has been performed to validate that the proposed Stimuplex® Onvision® system conforms its intended use and user needs. The

validation was performed with the following testing:

- Bench-top testing was performed in an artificial media to validate user need specification associated with system function and system performance such as:
  - Needle tip position
  - Connectivity
  - Power indicator
  - Battery
  - Boot-up time
  - System cable clip
  - Operational
  - Self-test
  - Needle tip not shown
- Preclinical testing on human cadaver was performed with physician (anesthesiologist) in a simulated clinical environment. The participants executed the test in the form of a system workflow to validate the intended use, user needs, and effectiveness of the safety related measure. As part of the validation, the implemented software was evaluated as part of the workflow. Results demonstrated all tests were passed.
- Usability evaluation in accordance with IEC 62366-1 was performed with anesthesiologist in a simulated use environment. Results from the usability evaluation demonstrated the proposed Stimuplex Onvision system is safe and effective for the intended use, users and use environment.

**CONCLUSION:**

The proposed Stimuplex Onvision system is substantially equivalent to the predicate devices, in terms of intended use, technological characteristics and safety and effectiveness.

Substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. Results of the functional and performance testing conducted on the proposed device demonstrate that the Stimuplex® Onvision® system complies with user need requirements as well as the requirements specified in the international and FDA-recognized consensus standards, and meets the acceptance criteria and is adequate for its intended use. It is considered substantially equivalent to the predicate device in terms of safety and effectiveness. The differences, between proposed device and predicate device, do not raise any new issues of safety and effectiveness. Therefore, proposed Stimuplex® Onvision® system is as safe and effective as predicate devices and substantially equivalent to the predicate devices.