Philips Medical Systems Nederlands B.V.
% Owen Callaghan, Ph.D.
Regulatory Affairs Officer
Veenpluis 6
Best, Noord Brabant 5684PC
NETHERLANDS

February 23, 2021

Re: K201743
Trade/Device Name: ClarifEye, ClarifEye Needle
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, LLZ, HAW
Dated: January 18, 2021
Received: January 22, 2021

Dear Dr. Callaghan:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201743

Device Name
ClarifEye; ClarifEye Needle

Indications for Use *(Describe)*
ClarifEye is intended to be an intra-operative image-guidance tool used during surgical and interventional therapy. It provides assistance to the performing physician to align a device with a virtual path that is planned on a 3D volume of the anatomy. This alignment is provided in the following ways:
-The virtual path is superimposed with a live video image of the area of interest.
-The position of the ClarifEye Needle is superimposed with the video images of the area of interest and/or the 3D images of the anatomy.
ClarifEye is intended to be used on patients who have been elected for procedures where a straight, rigid device is placed in the spine, such as sacral, lumbar and thoracic pedicle screw placement. ClarifEye is indicated for procedures where a reference to bony anatomical structures can be established using skin markers as a reference.

The ClarifEye Needle is a manual, surgical instrument intended to be used during spine surgery to facilitate placement of guidewires. The needle may be used as part of a planning and intraoperative guidance system (i.e. Philips intra-operative image guidance tool) to enable open or percutaneous image guided therapy. The ClarifEye Needle is indicated for use during posterior pedicle screw procedures, such as in the sacral, lumbar and thoracic spinal regions, in which the use of image guided surgery may be appropriate.
The ClarifEye Needle is EtO sterilized, for single use only and have to be disposed after use, according to local waste disposal methods for potentially bio hazardous material.

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

K201743

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

Date Prepared: June 22, 2020

Manufacturer:
Philips Medical Systems Nederland B.V. (**ClarifEye**)
Veenpluis 6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277

Primary Contact Person:
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Regulatory Affairs Officer
Phone: +31 641333263
E-mail: owen.callaghan@philips.com

Manufacturer:
Invivo Corporation, a division of Philips Medical Systems B.V. (**ClarifEye Needle**)
3545 SW 47th Ave
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USA
Establishment Registration Number: 1056069

Secondary Contact Person:
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Device:

Trade Name:	**ClarifEye**
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Regulation:	21CFR Part 892.1650
Classification Panel:	Radiology
Device Class:	Class II
Primary Product Code:	OWB (Interventional fluoroscopic x-ray system)
Secondary Product Code:	LLZ (System, image processing, radiological)
Tertiary Product Code:	JAK (System, x-ray, tomography, computed)
Quaternary Product Code:	OLO (Orthopedic stereotaxic instrument)

Predicate Device:

Trade Name:	*XperGuide*
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K131263 (July 24, 2013)
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Regulation:	21 CFR, Part 892.1650
Classification Panel:	Radiology
Device Class:	Class II

	Primary Product Code:	OWB (Interventional fluoroscopic x-ray system)
	Secondary Product Code:	LLZ (System, image processing, radiological)
Reference device 1:	Trade Name:	*XperCT*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K130893 (September 6, 2013)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	OWB (Interventional fluoroscopic x-ray system)
	Secondary Product Code:	JAK (System, x-ray, tomography, computed)
Reference device 2:	Trade Name:	*HeartNavigator*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K140138 (June 10, 2014)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	OWB (Interventional fluoroscopic x-ray system)
	Secondary Product Code:	LLZ (System, image processing, radiological)
Reference device 3:	Trade Name:	*Stryker SpineMap® 3D Navigation System*
	Manufacturer:	Stryker Leibinger GmbH & Company. KG
	510(k) Clearance:	K141941 (October 31, 2014)
	Classification Name:	Stereotaxic instrument
	Classification Regulation:	21 CFR, Part 882.4560
	Classification Panel:	Orthopedic
	Device Class:	Class II
	Primary Product Code:	OLO (Orthopedic stereotaxic instrument)
Accessory:	Trade Name:	**ClarifEye Needle**
	Classification Name:	Stereotaxic instrument
	Classification Regulation:	21CFR Part 882.4560
	Classification Panel:	Neurology
	Device Class:	Class II
	Primary Product Code:	HAW (Neurological Stereotaxic Instrument)
	Secondary Product Code:	KNW (Instrument, Biopsy)

Accessory Reference device 1:	Trade Name:	*Stryker KWIC Needle*
	Manufacturer:	Orthovita Inc.
	510(k) Clearance:	K140868 (Jun. 5, 2014)
	Classification Name:	Neurologic Stereotaxic Instrument, Biopsy Instrument, Biopsy
	Classification Regulation:	21 CFR, Part 882.4560
	Classification Panel	Surgical Devices
	Device Class:	Class II
	Product Code:	HAW (Neurological Stereotaxic Instrument) KNW (Instrument, Biopsy)
Accessory Reference device 2:	Trade Name:	MARROWMAX B ONE MARROW ASPIRATION NEEDLE KIT, MODELS 50083-XX, 50084-XX
	Manufacturer:	NEEDLETECH PRODUCTS, INC.
	510(k) Clearance:	K100665 (June 24, 2010)
	Classification Name:	Piston Syringe
	Classification Regulation:	21 CFR, Part 880.5860
	Classification Panel	General Hospital
	Device Class:	II
	Product Code:	FMF (Syringe, Piston)

Device Indications for Use:

ClarifEye has the following indications for use:

ClarifEye *is intended to be an intra-operative image-guidance tool used during surgical and interventional therapy. It provides assistance to the performing physician to align a device with a virtual path that is planned on a 3D volume of the anatomy. This alignment is provided in the following ways:*

- *The virtual path is superimposed with a live video image of the area of interest.*
- *The position of the ClarifEye Needle is superimposed with the video images of the area of interest and/or the 3D images of the anatomy.*

ClarifEye *is intended to be used on patients who have been elected for procedures where a straight, rigid device is placed in the spine, such as sacral, lumbar and thoracic pedicle screw placement.* ***ClarifEye*** *is indicated for procedures where a reference to bony anatomical structures can be established using skin markers as a reference.*

Accessory Indications for Use:

The ***ClarifEye Needle*** *is a manual, surgical instrument intended to be used during spine surgery to facilitate placement of guidewires. The needle may be used as part of a planning and intraoperative guidance system (i.e. Philips intra-operative image guidance tool) to enable open or percutaneous image guided therapy. The* ***ClarifEye Needle*** *is indicated for use during posterior pedicle*

screw procedures, such as in the sacral, lumbar and thoracic spinal regions, in which the use of image guided surgery may be appropriate.

*The **ClarifEye Needle** is EtO sterilized, for single use only and have to be disposed after use, according to local waste disposal methods for potentially bio hazardous material.*

Device description:

ClarifEye is a software medical device that is intended to be an intra-operative image-guidance tool used during surgical and interventional therapy.

It will be offered as an optional accessory to the Philips interventional fluoroscopic X-ray system, from which it receives 2D X-ray and video images. **ClarifEye** implements an automatic reconstruction (algorithm) to create 3D CBCT images from a rotational scan acquired on the X-ray system.

ClarifEye integrates the live video images of the surgical view and live 2D X-ray image which it overlays on the planned path shown in the reconstructed 3D CBCT image to provide navigational assistance, in real-time. **ClarifEye** provides assistance to the performing physician to align a device, such as a needle with a virtual path that is planned on a 3D image of the anatomy. The created 3D planning can be overlaid on live video images ("Augmented View") or live 2D fluoroscopy images, to monitor device deployment during the procedure.

ClarifEye is intended to be used in combination with the compatible **ClarifEye Needle** and **ClarifEye Markers**.

The **ClarifEye Needle** is for optional use only, when needle tip tracking is desired.

Device Technological characteristics:

ClarifEye employs the same fundamental technology as implemented in the currently marketed predicate device, *XperGuide (K131263).*
The fundamental technological are similar, such that both devices provide:

- Planning of the device positioning: define the entry point, size, path and target location of the device that will be inserted into the spine anatomy.
- Overlay of the 3D planning and 3D CBCT data on live (2D X-ray) fluoroscopy images provided by the Philips Interventional System, when desired by the user to guide device deployment during the procedure.
- Live image updates compensated for motion
- Device Tracking Function: real-time feedback to verify the position of the device being placed with respect to the planned path.
- Verification if the device is inserted at the correct location with fluoroscopic images and / or 3D CBCT reconstructions of the anatomy of interest.
- Provide archiving of images to DICOM compatible devices.

The technological differences are as follows:

- **ClarifEye** creates the 3D CBCT datasets instead of receiving them;
- **ClarifEye** provides the option to automatically segment 3D CBCT data.
- **ClarifEye** also provides the possibility to overlay the planning and 3D CBCT data on video images (so-called "Augmented View");
- Patient Motion Tracking Function extended: to ensure the overlaid images displayed during placement are continuously compensated for patient

movement, the position of accessory optical skin markers (*i.e*. **ClarifEye Markers**), placed on the skin around the region of interest are detected by **ClarifEye**.

- Device Tracking Function extended: **ClarifEye** detects the device position of a compatible device (*i.e.* **ClarifEye Needl**e) on the 3D image of interest, and displays this as a virtual representation. As the device is manoeuvred, it is automatically detected and the position displayed to the user, compared to the planned pathway. In *XperGuide*, the device position is estimated by inspection of the X-ray images.

These differences do not impact the safety and effectiveness of the device. Based on the information provided above, **ClarifEye** is considered substantially equivalent to the currently marketed and predicate device *XperGuide (K131263)* in terms of technological characteristics.

Accessory Description:

The **ClarifEye Needle** is a sterile, single use Bone Needle (150mm/OD 3mm /ID 2.3mm). Commonly used in open, minimally invasive, and percutaneous procedures with optical markers incorporated to be recognized by the Philips' stereotactic planning and intraoperative guidance system. **ClarifEye Needles** are equipped with black and white marker bands, an outer marked cannula with a "Madayag" tip, a blue ABS injection molded handle an inner stylet with three edge trocar tip.

Accessory Technological Characteristics

The ClarifEye Needle employs the same fundamental technology as implemented in the currently marketed *Stryker KWIC Needle (K140868).*
The fundamental technological are similar, such that both devices provide:

- Manual surgical instrument whos location can be tracked by software.
- Facilitates placement of guidewires
- May be used as part of a planning and intraoperative guidance system
- Used in spinal surgical procedures

The technological differences are as follows:

- The *KWIC Needle* is indicated for aspiration of autologous blood or bone marrow. **The ClarifEye Needle** does not support this indication.

These differences do not impact the safety and effectiveness of the device. Based on the information provided above, **ClarifEye Needle** is considered substantially equivalent to the currently marketed *Stryker KWIC Needle (K140868)* in terms of technological characteristics.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on **ClarifEye** and the **ClarifEye Needl**e demonstrate compliance with the following FDA recognized consensus standards and FDA guidance document(s):

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.1, 2015-06). FDA/CDRH recognition number 13-79.
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.0, 2015-02). FDA/CDRH recognition number 5-114.
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition. 2.0, 2007-03-01). FDA/CDRH recognition number 5-40,

- ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (Third Edition, 2016-11-01). FDA/CDRH recognition number 5-117,
- ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems. FDA/CDRH recognition number 11-251,
- NEMA PS 3.1-3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016). FDA/CDRH recognition number 12-300,
- ISO 11607-1 Packaging for terminally sterilized medical devices- Part 1: requirements for materials, sterile barrier systems and packaging systems (Second Edition, 2019-02). FDA/CDRH recognition number 14-530.
- ISO 11135 Sterilization of health-care products- Ethylene oxide- Requirements for the development, validation and routine control of a sterilization process for medical devices [including: Amendment 1 (2018)] Second Edition. FDA/CDRH recognition number 14-529
- ISO 10993-1 Biological Evaluation of medical devices- Part 1: Evaluation of medical devices within a risk management process (First Edition 2018-08). FDS/CDRH recognition number 2-258
- ISO 10993-5 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity (Third Edition, 2009-0-601). FDA/CDRH recognition number 2-245
- ISO 10993-7 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals [including Corrigendum 1 (2009)] (Second Edition 2008-10-15). FDA/CDRH recognition number 14-408
- ISO 10993-10 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization (Third Edition 2010-08-01). FDA/CDRH recognition number 2-174
- ISO 10993-11 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity (Third Edition 2017-09). FDA/CDRH recognition number 2-255
- *Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005 (document number 337),*
- *Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016 (document number 1757)*
- *"Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", October 2, 2014 (document number 1825),*
- *"Guidance for Industry and FDA Staff – Off-The-Shelf Software Use in Medical Devices", September 27, 2019 (document number 585)*
- *"Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", July 28, 2014 (document number 1766).*
- *"Guidance for Industry and FDA Staff – Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile", January 21, 2016 (document number 1615).*
- *"Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1, "Biological evaluation of medical devices- Part 1: Evaluation and*

testing within a risk management process", June 16, 2016 (document number 1811).

Non-clinical software verification testing has been performed to verify that all functional and non functional requirements of the System Requirements Specification, User Interaction Design as well as the identified safety Risk Control Measures from the Detailed Risk Management Matrix and the Privacy and Security requirements for **ClarifEye** have been implemented. Results demonstrated that all executed verification test passed.

The system has demonstrated a mean navigational accuracy of ≤ 2 mm for positional (tip) displacement and ≤ 2° for trajectory angle displacement according to ASTM F2554-10 in phantom tests.

A pig cadaver study demonstrated a mean accuracy of pedicle screw placement in thorocolumbar vertebrae by minimal invasive procedures with device tracking using the ClarifEye Needle of 2.0 ± 1.1 and 1.6 ± 0.8 mm at the screw tip and head, respectively. The mean angular accuracy was 1.7 ± 1.7° (axial) 1.6 ± 1.2° (sagittal).
A human cadaver study demonstrated a mean accuracy in minimal invasive thoracolumbar needle placement without device tracking of 2.2 ± 1.3 mm at the entry point/needle tip. The mean angular accuracy was 0.9 ± 0.8° (axial and sagittal).

Software validation testing has been performed to validate that **ClarifEye** conforms to its intended use, claims, user and service needs. The validation consisted of the following activities:

- Usability validation was performed with both orthopedic/neuro spine surgeons and monitoring nurse/technicians in a simulated use environment in a simulated environment. **ClarifEye** was found to be safe and effective for the intended use, users and use environment.
- In-house simulated use design validation was performed with Clinical Scientists/Marketing specialists that fulfill the intended user profile. The participants executed validation protocols in the form of a device workflow whereby a rigid instrument was placed in a spine object (phantom). Results demonstrated that all executed validation protocols were passed. **ClarifEye** conforms to its intended use and user needs.
- Service user needs validation was performed by a service engineer executing validation protocols covering service scenarios. Results demonstrated that all executed validation protocols were passed.
- The algorithms implemented in **ClarifEye** were evaluated as part of the clinical workflow in the in-house simulated use and usability validation studies.

Testing for the **ClarifEye Needle** accessory was performed to ensure that functional requirements have been met, and that core functions execute as expected.
A validation protocol simulating the clinical workflow was also executed to demonstrate that the **ClarifEye Needle** could be used as intended.
Usability evaluation survey in test environments that simulated the expected conditions of actual use was successfully executed by representative users.

Usability validation was performed with both orthopedic/neuro spine surgeons and monitoring nurse/technicians in a simulated use environment in a simulated environment. The **ClarifEye Needle** accessory was found to be safe and effective for the intended use, users and use environment.

Therefore results from usability demonstrate that the **ClarifEye Needle** is safe and effective for its intended use.

All these tests were used to support substantial equivalence of the subject device and demonstrate that **ClarifEye** and **ClarifEye Needle**:

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents, and
- Meets the acceptance criteria and is adequate for its intended use.

Based on the information provided above, **ClarifEye** is substantially equivalent to the currently marketed predicate device *XperGuide* in terms of safety and effectiveness.
Based on the information provided above, the **ClarifEye Needle** is substantially equivalent to the currently marketed *Stryker KWIC Needle* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The following performance data was provided as support of a marketing claim for the clinical accuracy.

Clinical data

A prospective planned, single arm, single center observational study with patients outside the United States eligible for spine procedures surgery in which patients would require pedicle screw placement.
The primary purpose of the study was to evaluate the accuracy of using the navigation software during open spine procedures.
Procedures included those such as: deformity correction (scoliosis/kyphosis), spinal fusion, degenerative disease requiring vertebral height correction, spondylolisthesis, stenosis (spinal of foraminal) and fractures.
Primary Objective:

- To estimate the accuracy of pedicle screw placement using Surgical Navigation on post-procedural CBCT
  Endpoint: Accuracy of screw placement was evaluated using a slightly adapted Gertzbein classification

Twenty (20) subjects enrolled in the study were included in the analysis of the primary objective. Scoliosis subjects corresponded to 65% of the total cohort including one post-operative revision surgery.

- The accuracy of pedicle screw placement using **ClarifEye** was 94.1% (238/253 accurately placed screws). Grading of pedicle screw placement was done according to the recognized Gertzbein classification for the lumbar and thoracic region and slightly adapted for the cervical screw placements. A grading 0 and 1 were seen as accurate placement.
- The mean accuracy between the distance between the planned path and device position at the tip of the screw and the screw head was 2.2 ± 1.56 mm and 2.0 ± 1.31 mm, respectively. The angular accuracy was 2.0 ± 2.0° (axial) 1.7 ± 1.5° (sagittal).

These results substantiates the clinical accuracy claim:
For open surgery, clinical accuracy of pedicle screw placement according to the Gertzbein scale is 94.1%.

Substantial Equivalence Conclusion:

ClarifEye is substantially equivalent to the currently marketed predicate device *XperGuide (K131263)* in terms of indications for use, technological characteristics and safety and effectiveness.

The **ClarifEye Needle** is substantially equivalent to the currently marketed *Stryker KWIC Needle* (K140868) in terms of indications for use, technological characteristics and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical tests provided in this 510(k) premarket notification. These tests demonstrate that **ClarifEye** and the **ClarifEye Needle** comply with the user need requirements as well as the requirements specified in the international and FDA-recognized consensus standards and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.
The clinical accuracy claim does also not impact the device from a safety and performance perspective. The clinical study demonstrates that **ClarifEye** provided with a marketing claim does not raise any new safety and/or effectiveness concerns.