

5 510(k) Summary

JAN 31 2014

[As Required by 21 CFR 807.92]

Manufacturer's Name and Address: mivenion GmbH
Robert-Koch-Platz 4
10115 Berlin
Germany
Phone: +49 30 6883792 0
Fax: +49 30 6883792 99
Mail: info@mivenion.com

Manufacturer Contact Information: Dr. Malte Bahner
mivenion GmbH
Robert-Koch-Platz 4
10115 Berlin
Germany
Phone: +49 30 6883792 11
Fax: +49 30 6883792 99
Mail: bahner@mivenion.com

Date 510(k) Summary Prepared: 2014 - 1 -29

Proprietary Name: Xiralite Fluorescence Imaging System X4

Common Name: Fluorescence Angiographic System

Regulation Description: Angiographic x-ray system

Regulation number: 21 CFR 892.1600

Product Code: IZI, OWN

Legally Marketed Predicate Devices:	Spy Fluorescent Imaging System (K042961, K073088), Novadaq Technologies Inc.
Device Description:	The Xiralite fluorescence imaging system X4 detects fluorescence signals in the defined field of view using a highly sensitive camera for signal detection and light emitting diodes (LEDs) for excitation. Fluorescence signals typically result from illumination of a specific fluorophore, the fluorescence dye indocyanine green (ICG), which is administered intravenously. Fluorescence signals are recorded at different periodical time points, thus the resulting images display an image sequence. The frame rate is between half a second and a few seconds, typically one second. The duration of the entire image acquisition is dependent on the pharmacokinetics of the administered fluorophore, with ICG typically six minutes.
Intended Use:	Acquiring fluorescence images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation.
Indications for Use:	Acquiring fluorescence images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation in hands.

Substantial Equivalence:

No.		Applicant Device Xiralite Fluorescence Imaging System X4	Predicate Device Spy Fluorescent Imaging System	Equivalence to Spy Fluorescent Imaging System
2. Application				
2.1	Intended Use	Acquiring fluorescent images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation	Capturing and Viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue transfer circulation in tissue and free flaps used in plastic-, micro- and reconstructive surgical procedures;	yes, the intended use is largely identical
2.2	Indications for Use	Acquiring fluorescent images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation in hands.	Capturing and Viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue transfer circulation in tissue and free flaps used in plastic-, micro- and reconstructive surgical procedures; Intra-operative visual assessment of the coronary vasculature and bypass grafts during coronary artery bypass (CABG) surgery	yes, the intended use is largely identical
2.3	Patient Population	For use in all patients	Patients with vascular or reconstructive surgery	yes, a part of the patient population is identical
2.4	Anatomic structures	Vascular bed, including microcirculation (hands)	Vascular bed, including microcirculation (intra-operative)	yes
2.5	Environments of use	Hospital, outpatient clinic, specialist office	Hospital	yes, a part of the environments of use is identical

No.		Applicant Device Xiralite Fluorescence Imaging System X4	Predicate Device Spy Fluorescent Imaging System	Equivalence to Spy Fluorescent Imaging System
2.6	User group	Health care professionals	Health care professionals	yes
5. Technology				
5.1	Principle	Interaction of radiation source with contrast dye	Interaction of radiation source with contrast dye	yes
5.2	Method of...	displaying the distribution of an injected contrast dye in the vascular system, including microcirculation, over time	displaying the distribution of an injected contrast dye in the vascular system, including microcirculation, over time	yes
5.3	Detector	CCD camera	CCD camera	yes
5.4	Field of View sufficient for intended use	Yes, field of view of 1200cm ² (40cm x 30cm) sufficient for intended use	Yes, field of view of 56cm ² (7.5cm x 7.5cm) sufficient for intended use	yes
5.5	Penetration depth sufficient for intended use	Yes, penetration depth of light estimated to be 2 to 4cm in vivo, sufficient for intended use	Yes, penetration depth of light sufficient for intended use	yes
5.6	Contrast dye required	Yes (ICG)	Yes (ICG)	yes
5.7	Components	Radiation source, detector, signal processing	Radiation source, detector, signal processing	yes
5.8	Materials with patient contact	All materials with patient contact are biocompatible and can be disinfected	No patient contact	n/a

**Rationale for Substantial
Equivalence:**

The comparison of the devices presented in the enclosed table demonstrates the substantial equivalence between the Xiralite fluorescence imaging system X4 and the predicate device. Like in most imaging procedures, the acquired images of the Xiralite fluorescence imaging system X4 as well as the images from the predicate device does not display a specific disease, but anatomical structures and their alteration by disease. The anatomical structure displayed by both devices is the vasculature, including the small vessels comprising the microcirculation. To enable this, both devices use the physical interaction of the output of a radiation source with a contrast dye injected into the vasculature. The generated radiation is focused on an anatomical region and displays the *in vivo* distribution of the contrast dye in the individual patient. All three devices are meant to be used solely by health care professionals.

**Nonclinical tests
Testing
in vitro testing:**

Non-clinical tests of the Xiralite fluorescence imaging system X4, covering mechanical, electrical and thermal safety, electromagnetic compatibility and biocompatibility, performed in accredited laboratories, have shown that the device is safe. These tests are performed according to consensus standards, therefore providing information with regard to the predicate devices, which were also tested according to the same applicable standards. Therefore, these tests provide further evidence of substantial equivalence in addition to the features presented in the enclosed table.

Furthermore we performed a test to show a linear dependence of the measured signal intensities of fluorescence optical imaging with the Xiralite fluorescence imaging system X4 with the concentration of the fluorophore ICG. The shown linearity of the measured fluorescence signal intensity further supports substantial equivalence with the predicate device Philips Integris Systems, Release 2.

**Clinical tests
In vivo testing:**

The Xiralite fluorescence imaging system X4 has a CE mark as a medical device for the European Union. Since 2009, more than 35 systems have been in clinical use in hospitals as well as in physician offices, mainly in Germany. On these systems, more than 10.000 patient exams have been performed without reported adverse events attributable to the Xiralite fluorescence

imaging system X4.

The feedback from users concludes that the device works as intended by safely providing fluorescence images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation.

According to the available feedback from current clinical users in Europe and the lack of reported adverse events attributable to the Xiralite fluorescence imaging system X4 it can be concluded that the Xiralite fluorescence imaging system X4 is a safe medical device and performs as intended, namely by providing fluorescence images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation. Overall, it does not pose any new questions regarding safety or effectiveness compared to the predicate device.

Conclusion:

As presented in the substantial equivalence comparison chart, the Xiralite fluorescence imaging system X4 and the predicate device have similar technological characteristics, and any minor differences do not raise different questions of safety or efficacy, as described in this submission. Furthermore, the Xiralite fluorescence imaging system X4 is at least as safe as the predicate device and performs as intended. This leads to the conclusion of substantial equivalence between the Xiralite fluorescence imaging system X4 and the predicate device.



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

January 31, 2014

Mivenion GmbH
Dr. Malte L. Bahner
Managing Director
Robert-Koch-Platz 4
Berlin, Germany, 10115

Re: K130003

Trade/Device Name: Xiralite Fluorescence Imaging System X4
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: IZI, OWN
Dated: January 27, 2014
Received: January 30, 2014

Dear Dr. Bahner:

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 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>. 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 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,

David Krause -S

for **Binita S. Ashar, M.D., M.B.A., F.A.C.S.**
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K130003

Device Name
Xiralite Fluorescence Imaging System X4

Indications for Use (Describe)
Acquiring fluorescent images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation in hands.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Neil R Ogden -S

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