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(as per 21 CFR §807.92)

YELLOW 560 Fluorescence Module

GENERAL INFORMATION

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Date prepared:	July 21, 2017
Device	System, X-Ray, Angiographic
Classification:	21 CFR 892.1600
Product Code and Class:	IZI - class II
Common Name:	Angiographic x-ray system
Trade/Proprietary Name:	YELLOW 560 Fluorescence Module

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PREDICATE DEVICES

Company:	Carl Zeiss Surgical GmbH
Device:	INFRARED 800 with FLOW 800 option (K100468)
Company:	Leica Microsystems
Device:	Leica FL800 (K061871)
Company:	Heidelberg Engineering GmbH
Device:	Heidelberg Retina Angiograph FA/ICGA (HRA/C) (K971671)

Reference Device

Company:	Novadaq Technologies, Inc.
Device:	SPY Intra Operative Imaging System: SP2000 (K072222)

INDICATIONS FOR USE (21 CFR §807.92(a)(5))

The ZEISS YELLOW 560 is a surgical microscope accessory used in viewing and visual assessment of intraoperative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels.

It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery.

DEVICE DESCRIPTION(21 CFR §807.92(a)(4))

The YELLOW 560 Fluorescence Module is an accessory to the ZEISS surgical microscope OPMI PENTERO 800 and OPMI PENTERO 900 for visualizing blood flow intraoperatively. The YELLOW 560 Fluorescence Module integrated into the OPMI PENTERO 800 / OPMI PENTERO 900 surgical microscope allows the surgical microscope to produce filtered light to illuminate the fluorescence properties of the sodium fluorescein dye and to detect the emitted fluorescent signal to examine the human vascular system during surgery. This is achieved by placing a filter in the illumination path and a second filter in the optical (viewing) path.

The filters of the YELLOW 560 Fluorescence Module are optimized to deliver excitation

wavelengths ranging from 460 to 500 nm and to emphasize fluorescence signals in wavelengths ranging from 540 to 690 nm that typically correspond to the excitation and emission spectrum of sodium fluorescein. The option to place the filters for YELLOW 560 is controlled via either the handgrip of the surgical microscope or the foot control.

Sodium fluorescein may be used as a fluorescence contrast agent to examine arteriovenous malformations (AVM), aneurysms, and vessel anastomoses. The dye helps to visualize intraoperative blood flow and vessel patency. Sodium fluorescein can be used as contrast agent with YELLOW 560 without changes to the formulation, mode of action, approved dose or route of administration.

RISK MANAGEMENT AND GENERAL SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. The YELLOW 560 Fluorescence Module description is integrated in the user manual of the OPMI PENTERO 800 / OPMI PENTERO 900 as it is an accessory to these devices.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by design means (hardware and software means), protection measures and user instructions. To confirm that the measures are effective and that the product meets its intended uses, verification of requirements and standards, and validation of the clinical workflow was performed. Carl Zeiss Meditec adheres to recognized and established industry practice and relevant international standards where indicated.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE (21 CFR §807.92(a) (6)):

The YELLOW560 Fluorescence Module is substantially equivalent to the primary predicate device, INFRARED 800 with FLOW 800 option (K100468). Each system utilizes the same surgical stereo microscope system. Each device utilizes a fluorescent agent to visualize blood flow and the fluorescence of the dye is displayed by using emission and excitation filters.

The indications for use for the YELLOW 560 Fluorescence Module is a subset of the previously cleared indications for INFRARED 800 with FLOW 800 option. The technological characteristics and operating principles of the YELLOW 560 Fluorescence Module are the same as that of the predicate device.

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The YELLOW 560 Fluorescence Module and INFRARED 800 with FLOW 800 option are both accessories to the OPMI PENTERO 800 and OPMI PENTERO 900 surgical microscopes. The microscope itself including the light source is identical. Both accessories (YELLOW 560 Fluorescence Module and INFRARED 800 with FLOW 800) have the same basic functions for viewing, recording, and replaying fluorescent images.

YELLOW 560 is an accessory to a surgical microscope, as is Leica's FL800 (K061871). Both offer functions regarding viewing, recording and replaying of fluorescent videos, both use illumination conditions for excitation and detection realized by filter and sensor specifications, and both use a fluorescent agent, Sodium Fluorescein with YELLOW 560 and Indocyanine Green (ICG) with Leica's FL800.

The YELLOW 560 utilizes a surgical stereo microscope while the Heidelberg Retina Angiograph (HRA) (K971671) uses a confocal laser scanning angiography system. While the systems are different, they each have the functions for viewing and recording fluorescent images. Both devices use Sodium Fluorescein as a contrast agent to visualize vascular structures – HRA for ophthalmic indications and YELLOW 560 for neurovascular indications. Both devices use filters that enable fluorescent images to be visualized after Sodium Fluorescein has been used as a fluorescent agent.

YELLOW 560 and Novadaq's SPY SP2000 (K072222) both provide the surgeon with the capability to view, record and replay fluorescent images of blood vessels. Both use a light source to illuminate the surface. Both use a fluorescent agent: Sodium Fluorescein with YELLOW 560 and Indocyanine Green (ICG) with Novadaq SPY. A fluorescent image results from the absorption of light causing excitation of the dye followed by emission of infrared energy. Both systems use a camera to capture the image. These images may then be used to evaluate the integrity of the vasculature.

Evaluation performed on the YELLOW 560 Fluorescence Module supports the indications for use statement and demonstrates that the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness.

SUBSTANTIAL EQUIVALENCE TO PREDICATE (21 CFR §807.92(B)(1)):

The OPMI PENTERO 800 / OPMI PENTERO 900 with YELLOW 560 Fluorescence Module has been tested to meet the product requirements (PRS) and software requirements (SRS) and is considered to be substantially equivalent to the predicates as indicated above.

Verification Testing to Standards

YELLOW 560 Fluorescence Module was designed and verified to the applicable standards. Testing was conducted on the YELLOW 560 Fluorescence Module and it was found to perform as intended. Each function and/or feature was tested by means of an appropriate test case or test specification.

Testing with the YELLOW 560 Fluorescence Module integrated in the OPMI PENTERO 900

surgical microscope has been conducted to demonstrate conformance to the following standards:

- ANSI / AAMI 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (3rd Edition) Electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (EMC)
- IEC 62471:2006 Photobiological safety of lamps and lamp systems
- IEC 60825-1:2007 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

Bench Testing
Internal verification testing was conducted to verify the optical performance of the YELLOW 560 Fluorescence Module, its fluorescent target and the system performance of the YELLOW 560 Fluorescence Module as integrated into the OPMI PENTERO 800 and PENTERO 900. The results indicate that the YELLOW 560 Fluorescence Module met all the requirements.

Verification and Validation
In addition to systems testing, software verification activities completed were divided into three phases:

- Tests accompanying development (including code inspections)
- Integration test phase – stabilization phase
- System verification

Validation and usability testing was conducted with the YELLOW 560 Fluorescence Module in conjunction with the OPMI PENTERO surgical microscope to ensure that the medical device meets the product and user requirements and to support a determination of substantial equivalence to the predicate devices.

Verification and validation activities were successfully completed and prove that the YELLOW 560 Fluorescence Module meets its requirements and performs as intended.

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Clinical Evaluation

Clinical data on YELLOW 560 has been collected by various researchers and is reported in the clinical literature. A review of the clinical literature that discusses the relevant studies has been included in this Premarket Notification. The review includes citations from peer-reviewed medical literature demonstrating the effective intraoperative use of the YELLOW 560 Fluorescence Module in sodium fluorescein angiography in the cerebrovascular area, especially in arteriovenous malformation (AVM) and aneurysm surgery.

One clinical publication provides a comparison of the YELLOW 560 Fluorescence Module used in combination with sodium fluorescein and the predicate device INFRARED 800 with FLOW 800 option used in combination with Indocyanine Green (ICG) in aneurysm surgery in the same patients.

In particular, the literature provides evidence of the effective real-time visualization of blood flow and visual assessment of vessel types in AVM surgery by the use of YELLOW 560. Moreover, it was demonstrated that YELLOW 560 was effectively used in the visual assessment of intraoperative blood flow in assessing cerebral aneurysms, vessel branch occlusion, as well as patency of very small perforating vessels in neurosurgery.

Comparing ICG videoangiography using INFRARED 800 with FLOW 800 option and fluorescein angiography using YELLOW 560, each technique exhibited specific attributes. YELLOW 560 provided an improved visualization of vasculature at high magnification in deep surgical fields and can be used within the full range of magnification whereas the INFRARED 800 with FLOW 800 option was considered especially beneficial for detection of blood flow within branching and small perforating vessels.

Specifically, the clinical literature supports the indications for use in demonstrating that the YELLOW 560 Fluorescence Module can be used and is beneficial:

- in viewing and visual assessment of intraoperative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels.
- to aid in the real-time visualization of blood flow and visual assessment of vessel types before and after arteriovenous malformation (AVM) surgery.

In summary, fluorescence angiography in the cerebrovascular area using the YELLOW 560 Fluorescence Module and INFRARED 800 with FLOW 800 option is considered comparable in terms of safety and effectiveness. Both methods are considered to be complementary to each other.

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510(K) SUMMARY (21 CFR §807.92(C)):

Based on the successful verification and validation testing and clinical literature review, it is Carl Zeiss Meditec AG's opinion that the YELLOW 560 Fluorescence Module, as an accessory to the OPMI PENTERO 800 / OPMI PENTERO 900 surgical microscope, does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

Additionally, all testing deemed necessary was conducted on the YELLOW 560 Fluorescence Module integrated into the OPMI PENTERO 800 / OPMI PENTERO 900 surgical microscope to ensure that the device is as safe and effective when used in accordance with its Instructions for Use as the predicate devices.