

K 100468

**SECTION 5.**

**510(K) SUMMARY**

**5. 510(K) SUMMARY**

**510(k) SUMMARY  
(per 21 CFR §807.92)**

MAR - 3 2010

**INFRARED 800 with FLOW 800 Option**

**GENERAL INFORMATION**

Manufacturer: Carl Zeiss Surgical GmbH  
Carl Zeiss Strasse 22  
73447 Oberkochen, Germany  
49 7364-20-2555 (phone)  
49 7364-20-2035 (fax)  
Est. Reg. No. 2431026

Contact Person: Judith A. Brimacombe, MA  
Director, Regulatory/Clinical Affairs  
Carl Zeiss Meditec Inc.  
5160 Hacienda Drive  
Dublin, California 94568  
(925) 557-4616 (phone)  
(925) 557-4259 (fax)

Date Summary Prepared: December 22, 2009

Classification name: System, X-Ray, Angiographic

Classification: 21 CFR 892.1600

Regulatory Class: II

Product Code: IZI

Trade/Proprietary name: INFRARED 800™ with FLOW® 800 option

**PREDICATE DEVICES**

Company: Leica Microsystems  
Device: Leica FL800  
(K061871, K080612)

Company: Novadaq Technologies, Inc.  
Device: SPY Intra Operative Imaging System: SP2000  
(K042961, K060867, K063345, K071037, K072222, K071619,  
K073088)

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### INTENDED USE

INFRARED 800 with the FLOW 800 option used during fluorescence guided surgery aids in viewing the visual assessment of intra-operative blood flow as well as vessel patency in surgical procedures in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery.

### INDICATIONS FOR USE

The Carl Zeiss Surgical INFRARED 800 with the FLOW 800 option is a surgical microscope accessory used in viewing and visual assessment of intra-operative 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. Likewise, INFRARED 800 with the FLOW 800 option used during fluorescence guided surgery aids in the visual assessment of intra-operative blood flow as well as vessel patency in bypass surgical procedures in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery.

### DEVICE DESCRIPTION

INFRARED 800 with the FLOW 800 option is an accessory to the OPMI Pentero surgical microscope for visualizing blood flow intraoperatively. INFRARED 800 allows the surgical microscope to produce light to illuminate the fluorescence properties of the Indocyanine Green (ICG) dye and to detect the emitted fluorescent signal to examine the human vascular system during surgery. FLOW 800 provides the surgeon with a processing mode that allows convenient handling and visualization of the INFRARED 800 video data.

### SUBSTANTIAL EQUIVALENCE

INFRARED 800 with the FLOW 800 option is substantially equivalent to the Leica FL800 and Novadaq SPY Intra Operative Imaging System. Each system utilizes either a surgical stereo microscope or angiographic optical imaging system, and has the same basic functions for viewing, recording, and replaying fluorescent images. Similar CCD cameras are utilized as sensors and the infrared options are equivalent. Each device utilizes the same type of fluorescent agent, Indocyanine Green (ICG), to visualize blood flow. Using white light and/or fluorescence and similar ICG excitation, realtime visualization of images takes place in equivalent transmission ranges.

The indications for use for INFRARED 800 with the FLOW 800 option are similar to the indications for use for the predicate devices cited in this application. A technological comparison and testing demonstrate that the INFRARED 800 with the

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FLOW 800 option is functionally equivalent to the predicate devices. Evaluation performed on the INFRARED 800 with the FLOW 800 option 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.

### CLINICAL EVALUATION

Clinical data on INFRARED 800 with the FLOW 800 option 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. It includes citations from peer-reviewed medical literature which documents that the Carl Zeiss Surgical INFRARED 800 accessory with Indocyanine Green (ICG) angiography has been used in hundreds of patients to visualize and assess blood flow for various types of surgeries including cerebral aneurysms, arteriovenous malformations (AVM), bypass surgery and free flap transfers.

The clinical report describes the following applications and findings for the INFRARED 800 accessory with the FLOW 800 option:

#### CEREBRAL ANEURYSMS:

- Assessment of cerebral aneurysm via evaluating complete or incomplete closure of aneurysm sac after clipping
- Visualization of aneurysm neck remnants
- Vessel branch occlusion via assessing flow of parent and branching vessels
- Evaluation of patency of very small perforating vessels not visible by digital subtraction angiography

#### AVMs:

- Detection of AVM vessels via real-time visualization of blood flow in feeding arteries, nidal vessels and draining veins

#### Bypass surgery and free flap transplantation:

- Assessment of patency of vessels joined by anastomosis in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery

### SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on INFRARED 800 with the FLOW 800 option to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

MAR - 3 2010

Carl Zeiss Surgical GmbH  
% Underwriters Laboratories, Inc.  
Mr. Ned Devine  
333 Pfingsten Road  
Northbrook, Illinois 60062

Re: K100468

Trade/Device Name: INFRARED 800™ with FLOW® 800 option  
Regulation Number: 21 CFR 892.1600  
Regulation Name: Angiographic x-ray system  
Regulatory Class: Class II  
Product Code: IZI  
Dated: February 11, 2010  
Received: February 18, 2010

Dear Mr. Devine:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". To the right of the signature, there are handwritten initials "D.R." and "D.R." written vertically.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**SECTION 4.**

**INDICATIONS FOR USE STATEMENT**

**4. INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K100468

Device Name: INFRARED 800™ with FLOW® 800 option

Indications for Use:

The Carl Zeiss Surgical INFRARED 800 with the FLOW 800 option is a surgical microscope accessory used in viewing and visual assessment of intra-operative 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. Likewise, INFRARED 800 with the FLOW 800 option used during fluorescence guided surgery aids in the visual assessment of intra-operative blood flow as well as vessel patency in bypass surgical procedures in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Neil R. [Signature]  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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