DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 19, 2014

Leica Biosystems Richmond, Inc.
Barbara-Ann Conway-Myers
Senior Regulatory Affairs Specialist
5205 Route 12
Richmond, Illinois 60071

Re: K141136
Trade/Device Name: Leica FL800
Regulation Number: 21 CFR 892.1600
Regulatory Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: IZI
Dated: May 16, 2014
Received: May 21, 2014

Dear Ms. Conway-Myers:

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: Enclosed

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141136

Device Name
Leica FL800

Indications for Use *(Describe)*
The Leica FL800 is a Leica Surgical Microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area and bypass grafts during coronary artery bypass (CABG) surgery, as well as blood flow during plastic and reconstructive surgery.

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)*

Section 5– 510(k) Summary of Safety and Effectiveness

Submitter
Leica Biosystems Richmond, Inc
5205 Route 12
Richmond, IL 60071
Barbara-Ann Conway-Myers – Contact Person
April 24, 2014 – Date Summary was Prepared

Device Name:

- Trade Name – Leica FL800
- Common Name – Fluorescent Angiographic System
- Classification Name – System, X-Ray, Angiographic per 21 CFR 892.1600
- FDA Product Code – IZI; subsequent product code is EPT (Surgical Microscope and Accessory)

Devices for Which Substantial Equivalence in Claimed:

- Leica Microsystems (Schweiz) AG, *Leica FL800 (K061871)*
- Leica Microsystems (Schweiz) AG, *Leica FL800 (K080612)*

Device Description:
The *Leica FL800* device is an accessory to the Leica surgical microscopes. It allows the surgical microscope to produce excitation light and resolve fluorescence light from the fluorescent agent ICG. The generated fluorescence signal depicts the distribution of the infra-red dye in the patient's blood vessels during the operation (fluorescence video angiography).

Intended Use of the Device:
The *Leica FL800* is a Leica Surgical Microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area, blood flow of the coronary vascular and bypass grafts during coronary artery bypass (CABG) surgery, as well as blood flow during plastic and reconstructive surgery.

Substantial Equivalence:
The *Leica FL800* is an existing device which was granted market clearance by the FDA following the submission of a 510(k) pre-market notification (K061871 and K080612). Leica Microsystems seeks only to include a variant of the *Leica FL800* which is a modification of the existing devices cleared under the two 510(k) mentioned above. There will be no change to the intended use of the device nor the alteration of the device's fundamental scientific technology.
The table below depicts the modifications associated with the *Leica FL800* variant.

Table 1: Comparison of Predicate devices (K061871 and K080612) to the Leica FL800 variant

		Proposed Accessory Description	
k061871	K080612	Leica FL800	Leica FL800 ULT
Standard Leica M520 OH3 Microscope (Class I exempt)	Additional Leica Surgical Microscopes available for use with the Leica FL800 as a result of extension to indications for use.	Accessory to Leica Surgical Microscopes intended for defined surgeries	
Sony XC-E1 50 NIR (near infra-red) camera (part of Leica FL800 upgrade)	No change	External NIR Camera ICG Filter	Dual Video Adaptor consisting of • Internal NIR Camera • ICG Filter • Beam Splitter
Leica Dual CCD Surgical Microscope Camera Adapter (part of Leica FL800 upgrade)	No Change	Dual Video Adaptor • Beam Splitter • Beam Mirror	
Leica modification of standard 300 Watt Xe light source (part of Leica FL800 upgrade)	Introduced possibility to use 400Watt Xe illumination as supplied on some Leica Surgical Microscopes	Light Source part of the Leica Surgical Microscope	
Leica FL800 electronic control unit (part of the FL800 upgrade)	No Change	No Change	No Change
ICG Fluorescence Dye (labelled for use with the Leica FL800)	No Change	Not part of the Leica System	

Standards Used in Demonstrating Conformance

The *Leica FL800* device is an accessory to the Leica surgical microscopes and as an accessory was not individually tested to any recognized standard. However, this accessary was tested in combination with the Leica surgical microscopes to demonstrate that it did not negatively impact the safety and effectiveness of the Surgical Microscope.

For Electromagnetic Compatibility (EMC) the Leica FL800 ULT has been tested and showed conformance to standard IEC 60601-1-2 Edition 3:2007.

For Electrical Safety the Leica FL800 ULT has been tested and showed conformance to standard IEC 60601-1 Edition 3:2005.

Conclusion

The modification of the Leica FL800 (variant) consists of the relocation of this accessory from an external configuration to an internal configuration which services 2 distinct advantages:

- It decreases the likelihood of any external disturbances to the Leica FL800 either by the surgeon or the operating room staff.
- The aesthetically pleasing design makes the device more ergonomic which is a value to the surgeon.

There is no alteration to either the intended use or the device's fundamental scientific technology and for this reason, Leica Microsystems seeks a Special 510k for the clearance of this device.