March 28, 2019

Leica Microsystems (Schweiz) AG
Georges Hakim
Director RA/QA
Max Schmidheiny-Strasse 201
CH-9435 Heerbrugg, Switzerland

Re: DEN180024
Trade/Device Name: Leica FL400
Regulation Number: 21 CFR 882.4950
Regulation Name: Diagnostic neurosurgical microscope filter
Regulatory Class: Class II
Product Code: QFX
Dated: April 24, 2018
Received: April 27, 2018

Dear Georges Hakim:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Leica FL400, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Leica FL400 is a surgical microscope accessory filter set for viewing fluorescence of fluorophores comprising an excitation filter for blue spectral range 380 nm – 430 nm and an observation filter comprising the long-wave blue, green, yellow and red spectrum in the spectral band greater than 444 nm.
>
> The FL400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III or IV gliomas during neurosurgery.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Leica FL400, and substantially equivalent devices of this generic type, into Class II under the generic name diagnostic neurosurgical microscope filter.

FDA identifies this generic type of device as:

> **Diagnostic neurosurgical microscope filter.** A diagnostic neurosurgical microscope filter is a device intended for use during neurosurgery to visualize fluorescence and enhance visualization of tissue associated with a specific disease or condition.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two

options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 27, 2018, FDA received your De Novo requesting classification of the Leica FL400. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Leica FL400 into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request and obtained interactively through email, FDA has determined that, for the previously stated indications for use, the Leica FL400 can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Incorrect or misinterpreted results, including: • False positive: visualization of fluorescence when in fact no target fluorophore is present • False negative: no visualization of fluorescence when in fact the target fluorophore is present	Non-clinical performance testing; and Labeling

In combination with the general controls of the FD&C Act, the diagnostic neurosurgical microscope filter is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, and verify and validate filter specifications and functional characteristics, including the following:
   (i) Spectrum and intensity of the illumination source;
   (ii) Spectrum of the excitation and emission filter modules when integrated in the surgical operating microscope;
   (iii) Excitation power and power density;
   (iv) Optical path loss from illumination source to objective lens or microscope camera;
   (v) Homogeneity of the excitation light at the focal plane;
   (vi) Fluorescence detection sensitivity;
   (vii) Verification of calibration or pre-operative procedures; and
   (viii) If camera-based, spectral sensitivity of the camera.

(2) Labeling must include:
   (i) Identification of the filter characteristics in conjunction with a compatible surgical operating microscope, to include the following:
      (A) Illumination spectrum and power density; and
      (B) Excitation and emission filter spectra.
   (ii) Instructions for calibration or pre-operative checks to ensure device functionality prior to each use;
   (iii) Instructions for use with compatible surgical operating microscopes, external light sources, and cameras;
   (iv) A warning that the device should only be used with fluorophores approved for use within the specified spectral ranges; and
   (v) A warning that the device is not a standalone diagnostic.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the diagnostic neurosurgical microscope filter they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Daryl Kaufman at 301-796-6467.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health