DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 5, 2017

Leica Microsystems (Schweiz) AG
Ms. Grainne Griffin
Senior RA Specialist
Max Schmidheiny-Strasse 201
Heerbrugg, Sankt Gallen, Switzerland 9435 CH

Re: K170239
Trade/Device Name: Leica FL560
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: June 5, 2017
Received: June 5, 2017

Dear Ms. Griffin:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

In addition, we have determined that your device kit contains Sodium Fluorescein which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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" (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 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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)*
K170239

Device Name
Leica FL560

Indications for Use *(Describe)*
The Leica FL560 is a surgical microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Overview

This 510(k) summary has been prepared in accordance with the requirements of 21CFR §807.92.

Trade Name	Leica FL560
Common Name	Fluorescent Angiographic System
Classification	Class II; Angiographic x-ray system (21 CFR 892.1600)
Product Code	IZI
Manufacturer	Leica Microsystems (Schweiz) AG., (Registration # 3003974370)
	Max Schmidheiny-Strasse 201
	Heerbrugg,
	Sankt Gallen 9435,
	Switzerland.
Contact Name	Grainne Griffin
Tel	+353 86 7710135
email	grainne.griffin@leica-microsystems.com
Predicate Device	Primary Leica FL800 ULT – clearance K141136
	Auxiliary Leica FL800 – clearance K061871 & K080612
Preparation Date	20th December 2016

Device Description

Similar to the predicate device (Leica FL800 ULT approved under K141136), the Leica FL560 is an accessory to the Leica Microsystems (LMS) Class I 510(k) exempt surgical operating microscope (SOM).

The Leica FL560 utilizes the illumination light source, supplied as standard with the SOM to produce excitation light which is filtered using an illumination filter (also referred to as the excitation filter) within the 460 - 500nm wavelength.

An observation filter is introduced into the observer light path within the optics carrier of the SOM to enable visualization of the resulting fluorescence emission comprising of the green, yellow and red spectrum in a spectral band above ~510nm.

Device Intended Use

The Leica FL560 is a surgical microscope accessory used in viewing fluorescence of fluorophores with an excitation peak between ~460 nm and ~500 nm (blue) and the fluorescence emission observation comprising the green, yellow and red spectrum in a spectral band above ~510 nm.

Device Indication for Use

The Leica FL560 is a surgical microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area.

Testing

Pre-clinical studies, human factors studies, electrical safety testing, and bench testing have been conducted to demonstrate the substantial equivalence of the Leica FL560 to the Leica FL800 ULT.

Summary Table

See 'Substantial Equivalence Summary Table: Comparison to Predicate Device' on following pages for a summary of all predicate and subject device comparative features and supporting substantial equivalence testing.

Conclusion

Based on the technological characteristics, principle of operation, intended use, environment of use, and indications for use, the Leica FL560 has been determined to be substantially equivalent to the predicate device, the Leica FL800 ULT (K141136) in terms of safety, effectiveness and performance.

Substantial Equivalence Summary Table: Comparison to Predicate Device

	Primary Predicate	Subject Device	
Device → What↓	Leica FL800 ULT (K141136)	Leica FL560 (Proposed new accessory)	Demonstration of Substantial Equivalence (SE)
SUMMARY OF GENERAL FEATURES			
Indications for use	**The Leica FL800 is a surgical Microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area** and by-pass grafts during coronary artery bypass (CABG) surgery, as well as blood flow during plastic and reconstructive surgery.	**The Leica FL560 is a surgical Microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area**.	Identical to subset of predicate indications for use
For use with	Standard Leica Surgical Operating Microscope M520 / M525 / M720 & M530 product range	Standard Leica M530 OH6/OHX Surgical Operating Microscope (Class I Exempt) Note: FL560 will not be available for the M520 / M525 / M720 SOM as these are older models scheduled for phase out	Identical to subset of predicate equipment platforms
Device Components	• Observation filter • Illumination filter • Filter housing ICG Filter • Beam Splitter • Built in Dual Video Adaptor consisting of Internal NIR Camera	• Observation filter • Illumination filter • Filter housing	Equivalent to subset of predicate components (filters equivalent but for different wavelength specifications)
Software	No Software	No Software	Identical
Required but not supplied	• Leica Surgical Microscope • Recording device	• Leica Surgical Microscope	Identical to subset of predicate
Drug	ICG	Fluorescein Sodium (fluorescein)*	Difference does not impact substantial equivalence, both drugs are fluorophores for visualizing blood flow and have longstanding FDA approvals

Device → What↓	Primary Predicate Leica FL800 ULT (K141136)	Subject Device Leica FL560 (Proposed new accessory)	Demonstration of Substantial Equivalence (SE)
SUMMARY OF GENERAL FEATURES, CONTINUED			
Illumination Filter [nm]	400 – 780nm	460 - 500nm	Equivalent, both are band pass filters with overlapping ranges
Observation Filter [nm]	800 – 880nm	Above ~ 510nm	Equivalent, the FL560 high pass filter range contains the FL800 band pass filter range
Light Source	Xenon 300 – 400watt	Xenon 400watt	Identical to subset of predicate
Test Card	Pre-operative check test card	Pre-operative check test card	Equivalent
Procedure Kit	None supplied	FL560 procedure kit containing: • AK-FLUOR (fluorescein) • FL560 test card • Procedure kit IFU	Difference does not impact substantial equivalence
**Reference Device CIS EyeScan Portable Modular Imaging System, K092374, also enables visualization of fluorescein (a technical feature of both the subject and reference device) for a different Indication for Use (ophthalmology imaging) but a generally equivalent intended use (fluorescence vascular angiography)*			
SUMMARY OF SUPPORTING TESTING			
Electrical Safety	Conformance to the following standards tested and confirmed: • IEC 60601-1:2005: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2:2007 (Modified): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests • IEC 60601-1-6:2010-06: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability	Conformance to the following standards tested and confirmed: • IEC 60601-1:2005: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2:2007 (Modified): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests • IEC 60601-1-6:2010-06: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability	Identical, both met all acceptance criteria

Device → What↓	Primary Predicate Leica FL800 ULT (K141136)	Subject Device Leica FL560 (Proposed new accessory)	Demonstration of Substantial Equivalence (SE)
SUMMARY OF SUPPORTING TESTING, CONTINUED			
Bench	Summary of Test Objective and Design: In house design verification testing was performed on FL560 to ensure that mechanical and functional requirements including design specifications were met. This was a protocol-driven verification with pre-established pass/fail criteria, ties to design specification and other quality and design control documents, and significant experiential basis drawn from the 10-year marketing history of predicate device FL800. As is typical for design verification, this was a one-arm study using only the subject device FL560 on microscope platform M530 OH6 and assessed vs. historical experience with predicate FL800 (historical control).		Equivalent Results: All tests completed met their pre-established acceptance criteria. Specifically, verification of (technical) Intended Use to produce light transference for an excitation peak between 460 nm and 500 nm and an observation peak above 510 nm was achieved. Review of FL560 test results vs. historical experience with predicate FL800 and vs. current QC standards for FL800 established that FL560 has functionally equivalent ability to produce excitation and observation peaks for use in viewing fluorescence of fluorophores intraoperatively on a Leica surgical microscope platform.
	Predicate Device: Historical controls via marketing and CAPA experience with predicate device FL800 were utilized instead of direct comparative testing.	Subject Device: • Filter specification: Filters were optically (spectrally), mechanically and geometrically assessed. Optical performance regarding spectral transmission and sufficiency of pass-through illumination was verified. • Mechanical: The Leica FL560 assembly geometric, mechanical, and functional integration into the Leica Microsystems M530 OH6 Surgical Operating Microscope was verified. • Labeling: Product labels and User Manual were reviewed for completeness, understandability, and accuracy.	

Device → What↓	Primary Predicate Leica FL800 ULT (K141136)	Subject Device Leica FL560 (Proposed new accessory)	Demonstration of Substantial Equivalence (SE)
SUMMARY OF SUPPORTING TESTING, CONTINUED			
Bio-compatibility	Not patient contacting, only external surface is anodized aluminum, so ISO 10993 testing is not applicable	Not patient contacting, only external surface is anodized aluminum, so ISO 10993 testing is not applicable	Identical
Preclinical	Summary of Test Objective and Design: A contracted, protocol-driven comparative preclinical study was prospectively performed to confirm that the subject device FL560 enabled viewing of intra-operative blood flow in the cerebrovascular area in a manner that was functionally equivalent to predicate device FL800ULT. Testing was completed at the University of Mainz, Germany Institute of Neurosurgical Pathology by neurosurgeons and veterinarians using test cases, pass/fail criteria, and independent scoring assessments that were predefined within the protocol. Six comparative image sets of the same cerebrovascular anatomy in either non-occluded (patent, native) or occluded (clipped) status and representative of neurosurgical procedures were visualized by both the FL560 and FL80ULT systems.		Results Summary: Equivalent The testing confirmed that the Leica FL560 meets the Indications for Use and provides functionally equivalent flow visualization to FL800ULT. All individual evaluations of comparative images confirmed that the Leica FL560 enabled visualization of intra-operative blood flow and vessel architecture in the cerebrovascular area in a functionally equivalent manner to the predicate device Leica FL800 ULT (n=18 comparative reviews, 100% confirmation). The FL560 additionally enabled concurrent visualization of background anatomical structures.
	Predicate Device: Data was collected using indocyanine green (ICG) fluorescent dye introduced into the vascular system of a porcine model. Data regarding the ability to visualize blood flow and vascular structures was collected and compared directly to data collected with the subject device Leica FL560 on the same porcine model and using Fluorescein Sodium (FS) fluorescent dye.	Subject Device: Data was collected using Fluorescein Sodium (FS) fluorescent dye introduced into the vascular system of a porcine model. Data regarding the ability to visualize blood flow and vascular structures was collected and compared directly to data collected with the predicate device Leica FL800ULT on the same porcine model and using ICG fluorescent dye.	

<table>
<tr><th>Device →
What↓</th><th>Primary Predicate
Leica FL800 ULT
(K141136)</th><th>Subject Device
Leica FL560
(Proposed new accessory)</th><th>Demonstration of Substantial Equivalence (SE)</th></tr>
<tr><td colspan="4">SUMMARY OF SUPPORTING TESTING, CONTINUED</td></tr>
<tr><td>Human Factors</td><td colspan="2"><u>Summary of Test Objectives and Design:</u> Human factors and usability testing was completed at the University of Utah Department of Neurosurgery using pre-defined test cases and objective pass/fail criteria pre-defined within the protocol. Two distinct user groups (neurosurgeons, nurses/techs) were assessed for their ability to perform specific clinical use demands. 15 users per group were assessed via observational analysis. The 10-year marketing history of predicate device FL800 and the FL560 risk analysis provided the basis for establishing key test elements and acceptance criteria.

The study was conducted in a simulated operating room and involved typical work flow scenarios including certain troubleshooting scenarios related to safety-critical tasks. Testing was conducted using a Leica Surgical Microscope fitted with the Leica FL560 module and using a cerebral vascular aneurysm phantom model flushed in with fluorescein and water in an alternating manner. Studies were conducted to reflect standard use cases, parameter adjustments, and interfaces encountered during routine use of the Leica FL560 module by surgeons and operating room personnel.

The study was designed in accordance with the published FDA guidance “draft Guidance for Industry and Food and Drug Administration Staff – Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 2011.</td><td rowspan="2"><u>Results Summary:</u>

Equivalent

Human factors testing confirmed that the FL560 usability was equivalent to Leica prior experience with FL800.

Similar controls and interfaces enabled 100% of users in both groups to perform key functions.

FL560 consistently visualized test card fluorescence and fluorescein fluorescence in a phantom vascular model.</td></tr>
<tr><td colspan="2"><u>Predicate Device</u>:

Historical controls via marketing and CAPA experience with predicate device FL800 were utilized instead of direct comparative testing.</td><td><u>Subject Device:</u>

Neurosurgeons performed tasks with the optics carrier (with control handle) containing the Leica FL560 observation filter and representative of their product interaction within the sterile field during surgery.

Circulating nurses performed tasks utilizing the interface screen outside of the sterile field before and during surgery.

Both groups performed test card verifications of FL560 function in accordance with User Manual instructions for preoperative checks.</td></tr>
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