March 14, 2024

NICO Corporation
Megan Becker
Senior Regulatory Affairs Specialist
250 East 96th Street, Suite 125
Indianapolis, Indiana 46240

Re: K232567
Trade/Device Name: Myriad SPECTRA Light Source
Regulation Number: 21 CFR 882.4950
Regulation Name: Diagnostic Neurosurgical Microscope Filter
Regulatory Class: Class II
Product Code: QFX
Dated: November 3, 2023
Received: November 8, 2023

Dear Megan Becker:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2024.03.14 12:58:10 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232567

Device Name
Myriad SPECTRA Light Source

Indications for Use *(Describe)*
The Myriad SPECTRA Light Source is an accessory to the Myriad System and delivers white light as well as excitation light for blue spectral range of 399 - 411 nm for use with an appropriate surgical microscope and fluorophore.
The Myriad SPECTRA Light Source is used to provide supplemental excitation light for fluorescent visualization of suspected grade III or IV gliomas during neurosurgery.

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.

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510(K) SUMMARY

Date Prepared: 11 March 2024

510(k) Number: K232567

Submitter/Manufacturer	NICO Corporation 250 E. 96th Street, Suite 125 Indianapolis, IN 46240
Primary Contact:	Megan Becker Sr. Regulatory Affairs Specialist Office: 317.660.7118 Email: regulatory@niconeuro.com
Trade Name	Myriad SPECTRA Light Source
Common/Usual Name	Diagnostic Neurosurgical Microscope Filter
Classification	21 CFR 882.4950 (Class II)
Product Code	QFX
Predicate Device	DEN180024, Leica FL400

Device Description

The Myriad SPECTRA Light Source used with the NICO Illumination Fiber and the NICO Delivery Sleeve delivers white light and 405 nm light to the surgical field when used with an appropriate surgical microscope and fluorophore. Surgical microscopes with the following characteristics are compatible with the Myriad SPECTRA Light Source:

- Includes an accessory used in fluorescent visualization of suspected grade III and IV gliomas during neurosurgery.
- The accessory enables viewing fluorescence of fluorophores with an excitation range between 380 nm – 430 nm and an observation band greater than 444 nm.

Indication for Use

The Myriad SPECTRA Light Source is an accessory to the Myriad System and delivers white light as well as excitation light for blue spectral range of 399 - 411 nm for use with an appropriate surgical microscope and fluorophore.

The Myriad SPECTRA Light Source is used to provide supplemental excitation light for fluorescent visualization of suspected grade III or IV gliomas during neurosurgery.

Comparison to Predicate

The Myriad SPECTRA Light Source is substantially equivalent to the Leica's FL400 (DEN180024). The subject device and the predicate device both enable the delivery of excitation light for visualization of suspected grade III and IV gliomas. The subject device is a new light

source with multiple outputs (white light and 405 nm light). This device and its capabilities, when evaluated individually or collectively, do not raise new questions of safety or effectiveness.

Technological Characteristics

The following table compares the subject device and predicate device.

Technological Characteristic Comparison

	Leica FL400 DEN180024	Myriad SPECTRA Light Source K232567
510(k) #	DEN180024	K232567
Regulation	§882.4950, QFX	§882.4950, QFX
Intended Use	Device intended for use during neurosurgery to visualize fluorescence and enhance visualization of tissue associated with a specific disease or condition.	SAME
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 of 380nm – 430nm and an observation filter comprising the long-wave blue, green, yellow and red spectrum it the spectral band greater than 444nm. The FL400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III or grade IV gliomas during neurosurgery.	The Myriad SPECTRA Light Source is an accessory to the Myriad System and delivers white light as well as excitation light for blue spectral range of 399 - 411 nm for use with an appropriate surgical microscope and fluorophore The Myriad SPECTRA Light Source is used to provide supplemental excitation light for fluorescent visualization of suspected grade III or IV gliomas during neurosurgery.
Type of Component	Accessory to a surgical microscope (microscope filter enabling excitation and emission)	Accessory to a surgical microscope (light source enabling excitation) Accessory to a tissue resection system (tool-mounted light)
Fundamental Technology	Consists of an excitation filter module and an emission filter module that are inserted into the optical beam path of a Xenon surgical microscope. Excitation filter module creates light that causes fluorescence of tissue containing an approved fluorophore. Emission filter module enhances fluorescence observed through microscope for visualization of fluorophore in neurosurgical field.	Consists of a high output LED light source that outputs either white light for general illumination or excitation light that causes fluorescence of tissue containing an approved fluorophore. Does not include an emissions filter or camera for detection of fluorescence. Must be used with an existing observation device (e.g., surgical microscope) intended for visualization of suspected grade III and IV gliomas during neurosurgery.
Principles of Use	Filtered light is delivered from and received by the microscope which is ~30 cm above the surgical field. FL400 is toggled on/off to deliver either white light or excitation light. Toggling is controlled by the end user of the microscope within the sterile field by using one of several configurable buttons/switches on the microscope. Intensity and other light characteristics are also controlled by the end user on the microscope.	Light source delivers light to surgical field through a fiber optic cable that is attached to Myriad resection handpiece tool. 405 nm light is toggled on/off to deliver either white light or excitation light. Toggling is controlled by the end user of the light source either within the sterile field using a foot pedal or outside the sterile field using the touch screen on the light source. Light intensity is controlled by the end user outside the sterile field using the touch screen on the light source.
Fluorescence Excitation Spectral Window	380 nm – 430 nm	405 nm center wavelength plus/minus 6 nm (399 nm – 411 nm)

The Myriad SPECTRA Light Source has similar principles of use and fundamental technology as the predicate. The technological and design differences do not raise new questions of safety or effectiveness and where applicable the nonclinical testing provides adequate means to assess the effects of the subject device as compared to the predicate.

Performance Testing

The performance of the Myriad SPECTRA Light Source was compared to the predicate device as part of performance testing to support substantial equivalence to the predicate device. The tests summarized in the table below were successfully completed to demonstrate that the Myriad SPECTRA Light Source met all applicable design and performance requirements and supports a determination of substantial equivalence.

Test	Test Method Summary	Results
Illumination Characteristics Testing	The following characteristics were measured for the Myriad SPECTRA Light Source: • Irradiance • Beam Profile • Spectral Analysis	Passed. Key characteristics of light from the Myriad SPECTRA Light Source were successfully measured.
General Performance Testing	General performance testing for the Myriad SPECTRA Light Source and Foot Pedal included the following: • Physical Characteristics (weights, dimensions, etc.) • Light Management • Operating Power • Noise The collective purpose of these tests is to confirm proper functionality of the Myriad SPECTRA Light Source and Foot Pedal.	Passed. Myriad SPECTRA Light Source and Foot Pedal satisfied all acceptance criteria related to physical characteristics, light management, operating power and noise.
Environmental Testing	Functionality of the Myriad SPECTRA Light Source and Foot Pedal was evaluated when subjected to ranges of altitude, humidity and temperature.	Passed. Myriad SPECTRA Light Source and Foot Pedal satisfied all acceptance criteria when subjected to various environmental conditions.
Software Verification and Validation	Verification and validation consisted of both hardware/system testing and software testing. This included the ability to select desired wavelengths, switching between wavelengths, intensity of light output, LCD touchscreen brightness, ability to change brightness, and	Passed. Software and/or hardware for Myriad SPECTRA Light Source and Foot Pedal satisfied all acceptance criteria. Additionally, regression testing was successfully completed.

Test	Test Method Summary	Results
	confirmation of system warnings. Regression testing was also conducted.	
Packaging Testing	Packaged Myriad SPECTRA Light Sources and Foot Pedals were subjected to the ISTA 2A test procedure and were then evaluated visually and functionally.	Passed. Myriad SPECTRA Light Source and Foot Pedal satisfied all visual and functional acceptance criteria after being subjected to ISTA 2A test procedure.
Electrical Safety Testing	Myriad SPECTRA Light Source and Foot Pedal were tested for electrical safety in accordance with IEC/UL/EN 60601-1, CAN/CSA C2.2 No. 601.1, and IEC/UL/EN 60601-1-2.	Passed. Myriad SPECTRA Light Source and Foot Pedal satisfied all applicable requirements related to electrical safety.
Biocompatibility	The NICO Illumination Fiber and NICO Delivery Sleeve are used with the Myriad SPECTRA Light Source to deliver light to the desired area. These are external communicating devices with limited (≤ 24 hours) contact with tissue/bone, neural tissue and CSF. The biocompatibility evaluation of these components was completed in accordance with ISO 10993 and the FDA biocompatibility guidance "Use of International Standard ISO 10993-1, "Biological valuation of medical devices - Part 1: Evaluation and testing within a risk management process"	Passed. Biocompatibility test results demonstrated that the NICO Illumination Fiber and NICO Delivery Sleeve meet the requirements from ISO 10993 and the FDA biocompatibility guidance.
Usability	Usability activities were conducted for the Myriad SPECTRA Light Source and Foot Pedal in accordance with IEC 62366. A usability engineering report was completed and includes all required elements, including but not limited to a Use Specification, User Interface Specification, Task List and Use FMEA.	Passed. All applicable usability activities were successfully completed for the Myriad SPECTRA Light Source and Foot Pedal.
	A usability/comparison study was completed for fluorescence induced by the predicate (FL400) versus the predicate with the Myriad SPECTRA Light Source to demonstrate that the user could consistently and accurately rank the level of fluorescence.	Passed. The usability/comparison study successfully demonstrated that he user can consistently and accurately rank the level of fluorescence when using the Myriad SPECTRA Light Source with a compatible surgical microscope.

Additionally, the Myriad SPECTRA Light Source is subject to special controls per 21 CFR 882.4950. Performance testing was completed to comply with all applicable special controls. A summary of these controls and related testing is outlined in the table below.

Control	Test Method Summary	Results
Spectrum and intensity of the illumination source	The spectrum and intensity of white light produced by the Myriad SPECTRA Light Source was measured and is included within the Illumination Characteristics Test Report.	Passed. The spectrum and intensity of white light produced by the Myriad SPECTRA Light Source were acceptable when compared to the predicate device.
Spectrum of the excitation and emission filter modules when integrated in the surgical operating microscope	The Myriad SPECTRA Light Source uses LEDs rather than filtered Xenon to produce the desired spectral ranges of light. The spectrum of the excitation light was measured and is included within the Illumination Characteristics Test Report.	Passed. The spectrum of excitation light produced by the Myriad SPECTRA Light Source was acceptable when compared to the predicate device.
Excitation power and power density	Maximum power density for the excitation light from the Myriad SPECTRA Light Source was measured and is included within the Illumination Characteristics Test Report.	Passed. The power density of the excitation light produced by the Myriad SPECTRA Light Source was acceptable when compared to the predicate device.
Optical path loss from illumination source to objective lens or microscope camera	Not applicable – the Myriad SPECTRA Light Source is not a microscope and does not include an objective lens or camera.	N/A
Homogeneity of the excitation light at the focal plane	Homogeneity of excitation light for the Myriad SPECTRA Light Source was assessed through beam profile measurements. Optical power was measured at various increments along the x and y axes of the light produced by the Myriad SPECTRA Light Source. The optical power measurements were then plotted to demonstrate the distribution of power. Results are included within the Illumination Characteristics Test Report.	Passed. Homogeneity of the excitation light at the focal plane produced by the Myriad SPECTRA Light Source was acceptable when compared to the predicate device.
Fluorescence detection sensitivity	Not applicable – the Myriad SPECTRA Light Source is not a camera and does not have fluorescence detection capabilities.	N/A
Verification of calibration or pre-operative procedures	The light output produced by the Myriad SPECTRA Light Source was tested to ensure its stability for a maximum number of hours. Results are included within the General Performance Test Report.	Passed. Stability of light output produced by the Myriad SPECTRA Light Source was determined to be acceptable over a maximum number of hours. Stability must be confirmed prior to each surgical case.

Control	Test Method Summary	Results
	Prior to each surgical case, the operator's manual instructs the end user to check the accumulated number of hours for light output from the Myriad SPECTRA Light Source to confirm that the maximum number of hours has not been exceeded.	
If camera-based, special sensitivity of the camera	Not applicable – the Myriad SPECTRA Light Source is not camera-based.	N/A

Conclusion

The subject device and the predicate device are equivalent in terms of intended use and technological considerations. Risk assessments and performance testing have demonstrated that the design differences between the subject and the predicate device do not raise different questions of safety or effectiveness. Therefore, the Myriad SPECTRA Light Source is substantially equivalent to the legally marketed predicate device Leica FL400.