OnLume Inc.
Mr. Greg Bange
Senior Manager - Regulatory Affairs and Quality Assurance
3300 Commercial Ave
Madison, Wisconsin 53714

January 17, 2020

Re: K192761
Trade/Device Name: Asimov-MKS Imaging System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: December 18, 2019
Received: December 20, 2019

Dear Greg Bange:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Neil R.P. Ogden
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192761

Device Name
Asimov-MKS Imaging System

Indications for Use *(Describe)*

The Asimov-MKS Imaging System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after vascular, gastrointestinal, organ transplant, plastic, reconstructive, and micro surgeries.

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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3300 Commercial Ave
Madison, WI 53714
www.onlume.com

Section 8 510(k) Summary

Submitter

OnLume Incorporated
3300 Commercial Avenue
Madison, WI 53714
Phone: 888-751-5131
Contact: Greg Bange
Date Prepared: December 18, 2019

Device Identification

Device Name:	Asimov-MKS Imaging System
Trade Name:	Asimov-MKS Imaging System
Common Name:	Fluorescence Angiography System
Regulation Number:	21 CFR 892.1600
Regulation Description:	Angiographic x-ray system
Regulation Name:	System, X-Ray, Angiographic
Regulatory Class:	Class II
Product Code:	IZI

Predicate Device

SPY Elite® Intraoperative Perfusion Assessment System – K182907

Reference Devices

No reference devices were used in this submission.

Device Description

The Asimov-MKS Imaging System is a fluorescence angiography imaging system. It is a prescription device intended to be used in hospital surgical suites, ambulatory surgery centers, and similarly equipped healthcare facilities. The Asimov-MKS Imaging System consists of an imager mounted to the distal end of an articulated arm that is affixed to a mobile cart.

Under the supervision of the surgeon, the imager illuminates a region of interested with near infrared and/or white light. Cameras, integral to the imager, acquire fluorescence and/or white light color images and direct the acquired images to processing hardware within the cart.

The articulated arm allows the imager to be directed at the region of interest. The arm affords unencumbered access to the patient and permits the cart to be positioned outside of the sterile field.

The cart allows the Asimov-MKS Imaging System to be positioned as needed for a surgical procedure and to be relocated within a facility for additional procedures or storage. The cart houses the processing hardware that display and record the acquired images. Software executed on the

processing hardware provides secondary functions such as patient biographical data entry, image review, and data archive.

To maintain the sterile surgical field, a sterile drape covers the imager and portions of the arm during clinical use. The single use drape streamlines device cleaning after use.

The fluorescent imaging agent utilized is indocyanine green (ICG). ICG is injected into the patient's blood stream, rapidly binds to the blood plasma, and is transported on the blood from the injection point to the region of interest. The ICG fluoresces when illuminated with the near infrared light emitted by the imager. Images of the fluorescence allow the clinician to visually assess circulation and related tissue perfusion.

Indications for Use / Intended Use

The Asimov-MKS Imaging System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after vascular, gastrointestinal, organ transplant, plastic, reconstructive, and micro surgeries.

Technological Characteristics

The subject and predicate devices employ the same fundamental scientific principles and have substantially equivalent technological characteristics. The predicate and subject devices have functionally equivalent subsystems for the imager, articulated arm, and mobile cart. The subject device illuminates the surgical field with infrared light of the same wavelength as that of the predicate device. The predicate device uses ambient room light when capturing a color image, whereas, the subject device utilizes both ambient light and the integral white LEDs during color imaging. Both the subject and predicate devices are draped during surgical use and utilize ICG as the fluorescent agent. Neither device is intended to contact the patient during use.

Two operational differences between the predicate and the Asimov-MKS Imaging System are:

- The Asimov-MKS Imaging System supports the real-time display of combined white-light color and fluorescence images (i.e. fluorescence overlaid on color images). Thus, the user may assess blood flow and tissue perfusion as indicated in the fluorescence images referenced directly to the anatomy as indicated in the white-light color images during the surgical procedure. The predicate device does not support the real-time display of overlaid images.
- The Asimov-MKS Imaging System is able to acquire fluorescence images with no changes in the ambient lighting of a typical surgical suite. The predict device requires that the surgical suite be darkened during fluorescence image acquisition.

The following table compares key attributes of the Asimov-MKS Imaging System to those of the predicate device.

Attribute	Subject Device	Predicate Device
Trade Name	Asimov-MKS Imaging System (subject to change when placed on the market)	SPY Elite® Intraoperative Perfusion Assessment System – K182907
Common Name	fluorescence angiography imaging system	fluorescence angiography imaging system
Product Code	IZI (21 CFR 892.1600)	IZI (21 CFR 892.1600)
Regulation Device Name	System, X-Ray, Angiographic	System, X-Ray, Angiographic
Combination Product	No (used with equivalent third-party items)	Yes
Fluorescence agent	indocyanine green (ICG)	indocyanine green (ICG)
Fluorescence Excitation Source	Infrared laser diode 805 nm 55mW (at laser aperture)	Infrared laser diode 805 nm 119mW (at laser aperture)
Fluorescence Detector	CMOS	CCD
Fluorescence Detector Output	12 bits/pixel 1024 x 768 (pixels/frame)	8 bits/pixel 1024 x 768 (pixels/frame)
Fluorescence Frame rates	Display rate: 30 fps Capture/Record rate: 30 fps	Display rate: 30 fps Capture/Record rate: 30, 15, 7.5, or 3.75 fps (user selected)
Fluorescence record capacity (continuous real-time image record	Up to 160,000 frames	Up to 1024 frames
White Light Excitation Source (for color images)	Integral LED and Ambient	Ambient
White Light Detector	CMOS	CCD
White Light Detector Output	8 bits/pixel 1024 x 768 (pixels/frame)	8 bits/pixel 1024 x 768 (pixels/frame)
White Light Frame rates	Display: 30 fps Record: 30 fps and single snapshot image	Display: 30 fps Record: Single snapshot image
White Light record capacity (continuous real-time image record)	Up to 160,000 frames	1 frame per snapshot
Working distance (cm)	30	30
Field of View (cm2)	266 (19 x 14)	266 (19 x 14)
Output dimensions (in pixels)	1024 x 768	1024 x 768

Attribute	Subject Device	Predicate Device
Display Bit Depth	8	8
Real-time Color image with Fluorescence Overlay	Yes	No
Ambient Light Level	High (room lights on)	Low (room lights off)
Mobile	Yes	Yes
Power Source	Wall	Wall[1]
Patient contact (w/ imaging device)	None	None
Consumables (single use)	Sterile Drape, ICG	Sterile Drape, ICG
Operating System	Linux	Windows
Report Generation	Various formats and data	Various formats and data
Data Archive	WiFi export	USB export

[1]The predicate device has battery support for completion of image data record in the event of a wall power failure. Battery support is unnecessary in the subject device as images are recorded in real-time.

Performance Data

Results of verification and validation testing performed by OnLume Inc. confirm the Asimov-MKS Imaging System conforms to design specifications and meets the needs of the intended users. Additionally, testing performed by an independent certified testing laboratory demonstrates the device complies with the requirements of applicable FDA recognized consensus safety standards for medical devices as listed in the following table.

Applicable Standards		
Standard Number (Edition and Publication Date)	Title	FDA Recognition number
IEC 60601-1:2005 + A1:2012 (ed 3.1 2012-08)	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2:2014 (ed 4.0 2014-02)	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and test	19-8
IEC 60601-1-6:2010 + A1:2013 (ed 3.1 2013-10)	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability	5-89

Applicable Standards		
IEC 60825-1:2007 (ed 2.0, 2007-03)	Safety of laser products –Part 1: Equipment classification and requirements	12-273
IEC 62471 (ed. 1.0, 2006-07)	Photobiological safety of lamps and lamp systems	12-249

In aggregate the test results and associated performance data demonstrate that the Asimov-MKS Imaging System is equivalent and performs at least as well as the predicate device.

Conclusion

The Asimov-MKS Imaging System is substantially equivalent to the predicate device. The devices have the same intended use and the same technological characteristics. The technological differences that exist do not raise new types of safety or effectiveness questions. Further, results of performance testing demonstrate the Asimov-MKS Imaging System is equivalent to the predicate.