INTRADYS
Tiffany VAZ
Head of Quality and Regulatory Affairs
37 rue Jean Marie Le Bris
BREST, 29200
FRANCE

May 2, 2025

Re: K243069
Trade/Device Name: LUMYS (V1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 27, 2024
Received: March 28, 2025

Dear Tiffany VAZ:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jessica Lamb, PhD
Assistant Director,
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243069

Device Name
LUMYS (V1)

Indications for Use *(Describe)*
LUMYS is intended for use as a software interface and image segmentation system, which is used to carry out pre-surgical planning tasks. LUMYS is intended to be used by clinicians with appropriate clinical judgement.

LUMYS is a medical display software intended for 3D image visualization and image interaction. The stereoscopic 3D images are generated from 3D volumetric data acquired from a CT scan source. The device is intended to provide visual information to be used by clinicians with appropriate clinical judgement for analysis of surgical options, and the intraoperative display of the images. The primary surgeon wears a Microsoft Hololens™ Head Mounted Display (HMD) and consults with external users who can perform pre-surgical tasks such as annotating 3D images, uploading files and speaking with the surgeon. The surgeon must cease communication once surgery begins.

LUMYS is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. LUMYS is intended to be used as a reference display consultation software, which assists the clinician with appropriate clinical judgement who is responsible for making all final patient management decisions.

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.

K243069

510(k) SUMMARY

Contact Details

Applicant Name : INTRADYS

Applicant Address : 37 rue Jean Marie Le Bris – 29200 BREST – France

Applicant Contact Telephone : +33 2 98 43 39 03

Applicant Contact ; Mrs. VAZ Tiffany

Applicant Contact Email: tiffany@intradys.com

Device Name

Device Trade Name : LUMYS (V1)

Common Name: Medical image management and processing system

Classification Name: System, Image Processing, Radiological

Regulation Number: 892.2050

Product Code(s): LLZ

Legally Marketed Predicate Devices

Predicate #	*Predicate Trade Name (Primary Predicate is listed first)*	*Product Code*
K221796	Cysware 4H and Cysart 4H	LLZ

Device Description Summary

LUMYS is a data visualization standalone software that is used during medical procedures to visualize medical data and share this visualization with other healthcare professionals attending remotely the procedure. Different components are involved:
- A Microsoft HoloLens 2 headset to access the data in the operating theater,
- A broadcasting computer to broadcast video from a medical imaging device in LUMYS,
- A web browser on a computer to access the data remotely.

LUMYS is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. LUMYS is intended to be used by clinician with appropriate clinical judgement.

Intended Use / Indications for Use

LUMYS is intended for use as a software interface and image segmentation system, which is used to carry out pre-surgical planning tasks. LUMYS is intended to be used by clinicians with appropriate clinical judgement.

LUMYS is a medical display software intended for 3D image visualization and image interaction. The stereoscopic 3D images are generated from 3D volumetric data acquired from a CT scan source. The device is intended to provide visual information to be used by clinicians with appropriate clinical judgement for analysis of surgical options, and the intraoperative display of the images. The primary surgeon wears a Microsoft Hololens™ Head Mounted Display (HMD) and consults with external users who can perform pre-surgical tasks such as annotating 3D images, uploading files and speaking with the surgeon. The surgeon must cease communication once surgery begins.

LUMYS is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. LUMYS is intended to be used as a reference display consultation software, which assists the clinician with appropriate clinical judgement who is responsible for making all final patient management decisions.

Indications for Use Comparison

LUMYS and the predicate device have the same indications.

Intended use of both medical devices remains the same, i.e. : to import, visualize, annotate, segment medical images, and to display and manipulate 3D images in mixed reality.

Technological Comparison

LUMYS and the predicate device are identical for most of the characteristics that were considered. In particular, both use Microsoft HoloLens 2 as the user interface in the operating room. In this context, optical and display bench testing was carried out on the system Microsoft HoloLens 2 and LUMYS.

When the devices were found to be not identical, the substantial equivalency was demonstrated, and safety and effectiveness were not negatively affected.

Non-Clinical and/or Clinical Tests Summary & Conclusions

LUMYS has been developed, verified and validated in accordance with FDA guidelines, IEC62304/A1:2016, IEC 81001-5-1:2021, IEC 82304-1:2016.

The testing results that all specifications have met the acceptance criteria. LUMYS passed all the tests, and support the claims of substantial equivalence, safety and effectiveness for its intended use.

The usability assessment of LUMYS has been carried out according to FDA guidelines, IEC 62366-1:2015+Amd1:2020 and ISO14971:2019. The Validation demonstrates that LUMYS meets clinician's needs, including in terms of user interface.

Equivalency to the predicate device was possible with output data of the software development, in particular with SRS, functional testing, optical testing and validation of the segmentation algorithm.

Optical testing was carried out according to IEC 63145-20-20. Results confirm that LUMYS is well suited to visualize medical images such as DICOM in Microsoft Hololens™ Head Mounted Display. Other tests, carried out to validate the segmentation algorithm, show that LUMYS' segmentation algorithm allows to segment DICOM from CT scan source with an error lower than 0.9 mm.

LUMYS has the same intended use and the same technological characteristics that the predicate device.

It can be demonstrated that both devices are substantially equivalent, and that LUMYS doesn't raise additional questions regarding security and effectiveness compared to a legally market predicate devices.