Imaging Biometrics, LLC
℅ Mr. Timothy Dondlinger
COO
13416 Watertown Plank Road, Suite 260
ELM GROVE WI 53122

October 29, 2020

Re: K201092
Trade/Device Name: LSN
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: September 22, 2020
Received: September 24, 2020

Dear Mr. Dondlinger:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201092

Device Name
LSN

Indications for Use *(Describe)*
LSN (Liver Surface Nodularity) is an image analysis software application intended to assist radiologists and other trained healthcare professionals in analyzing and reporting on the liver morphology depicted in computed tomography (CT) images for use in assessment of chronic liver disease. LSN is designed to assist the user in the evaluation and documentation of liver morphology, specifically liver surface nodularity, provided that the surface nodularity is adequately depicted on the CT images.

LSN provides quantitative metrics related to liver fibrosis by automating segmentation of the liver surface within user-defined Regions of Interest (ROIs) and calculating distances and means related to the liver surface nodularity. LSN also offers reporting capabilities for documenting user-confirmed results, thereby facilitating communication with other trained healthcare professionals and assessment of changes over time.

LSN is intended to provide image-related information that is interpreted by a trained professional, but it does not directly generate any diagnosis. The information provided by LSN should not be used in isolation when making patient management decisions.

LSN is not intended for use with or for the diagnostic interpretation of mammography images.

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

510(k) Notification K201092

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant / Owner :	Imaging Biometrics, LLC 13416 Watertown Plank Road, Suite 260 Elm Grove, WI 53122
Contact Person:	Timothy Dondlinger (262) 439-8252 (telephone) (262) 439-8301 (fax) tim@imagingbiometrics.com
Date Prepared:	April 17, 2020
Common Name:	System, X-Ray, Tomography, Computed
Trade Name:	LSN
Classification Name:	Computed Tomography X-Ray System
Review Panel:	Radiology
Regulation Number:	892.1750
Device Class:	II
Product Code:	JAK
Subsequent Product Code	LLZ (892.2050; System, Image Processing, Radiological; Picture Archiving and Communications System)

Predicate Device Information

Type	510(k)	Trade Name	Manufacturer	Regulatory Citation (21 CFR)	Regulation Name	Regulatory Class	Primary Product Code
Primary Predicate	K133649	Hepatic VCAR	GE Medical Systems SCS	892.1750	System, X-Ray, Tomography, Computed	II	JAK
Secondary Predicate	K101342	OsiriX MD	Pixmeo SARL	892.2050	System, Image Processing, Radiological	II	LLZ

Device Description

LSN (Liver Surface Nodularity) is a post-processing software application which assists trained professionals in evaluating DICOM computed tomography image studies of patients with chronic liver disease. The software provides tools to enable the user to make quantitative measurements related to liver surface nodularity as depicted on CT images.

The generated information consists of a LSN Score (reported in tenths of a millimeter), a quantitative measure of the surface nodularity based on a set of user-defined ROIs sampling the liver surface. LSN calculates the distance between the detected liver edge and a smoothed polynomial line (spline) on a pixel-by-pixel basis inside user-painted ROIs and reports the mean of these distances on a per-slice basis as well as an overall LSN Score for the imaging series.

LSN provides the user with information that may assist in evaluating the progression of chronic liver disease. LSN does not make clinical decisions and the information provided by LSN must not be used in isolation when making patient management decisions. The LSN Score may provide value by standardizing terminology used to describe surface nodularity in radiological reporting, thereby facilitating communications between radiologists and other clinicians involved in a patient's treatment planning. In addition, standardized reporting metrics may also be helpful in assessing changes for the same patient over time.

LSN functions by displaying a DICOM CT abdominal series to the user and the user paints a broad region of interest (ROI) delineating the liver edge on a subset of image slices. Then, for the painted region on each slice, the edge is detected using multiple algorithms. For each detected

edge, a spline is fit to the edge and the shortest distances from each edge pixel to the spline are calculated and averaged, resulting in a potential LSN value. The maximum LSN value calculated for an edge is reported as the LSN value for that edge. The LSN values for all slices on which ROIs have been painted are then averaged to determine the overall LSN score.

The core LSN algorithms are implemented in platform-independent code, and have been integrated into both a standalone PC research application and a Mac-based viewer plugin for clinical use. Both platforms produce an equivalent LSN score; the clinical version alters the algorithm to require less re-work by the user. The clinical version also produces a report containing images of the painted slices, the scores for each slice, and the overall LSN score. The report is produced in both PDF and DICOM formats and is ready for upload to PACS.

Indications for Use/Intended Use Statement

LSN (Liver Surface Nodularity) is an image analysis software application intended to assist radiologists and other trained healthcare professionals in analyzing and reporting on the liver morphology depicted in computed tomography (CT) images for use in assessment of chronic liver disease. LSN is designed to assist the user in the evaluation and documentation of liver morphology, specifically liver surface nodularity, provided that the surface nodularity is adequately depicted on the CT images.

LSN provides quantitative metrics related to liver fibrosis by automating segmentation of the liver surface within user-defined Regions of Interest (ROIs) and calculating distances and means related to the liver surface nodularity. LSN also offers reporting capabilities for documenting user-confirmed results, thereby facilitating communication with other trained healthcare professionals and assessment of changes over time.

LSN is intended to provide image-related information that is interpreted by a trained professional, but it does not directly generate any diagnosis. The information provided by LSN should not be used in isolation when making patient management decisions.

LSN is not intended for use with or for the diagnostic interpretation of mammography images.

Substantial Equivalence

The below table provides a comparison summary of the subject device's Indications for Use/Intended Use Statement to the primary and secondary predicate devices.

Indications for Use / Intended Use	**Subject**	**Primary Predicate:** **Hepatic VCAR**	**Secondary Predicate:** **OsiriX MD**	**Rationale for Substantial Equivalence**
LSN (Liver Surface Nodularity):				
1. is an image analysis software application	Yes	Yes	Yes	Same
2. intended to assist radiologists and other trained healthcare professionals	Yes	Yes From p.16 of the User Manual: *"Intended Operator Profile: Hepatic VCAR is designed for clinicians, specifically, radiologists, interventional radiologists, surgeons, and other trained healthcare professionals (3D technologists). Clinicians and healthcare professionals using this software must be educated in the reading and quantitative and qualitative analysis of CT liver exams."*	Yes	Same
3. in analyzing and reporting on computed tomography (CT) images	Yes	Yes	Yes (multimodality; CT included)	Same
4. for assessment	Yes	Yes	Yes	Same
5. in chronic liver disease.	Yes	Yes (Not explicitly stated, but implied. Chronic liver disease is frequently a precursor for liver lesions, e.g. hepatocellular carcinoma).	Yes (Not specifically claimed in the Intended Use statement, but implied: General image viewing and analysis application for all patients).	Same. Chronic liver disease is a subset of the intended patient population for Hepatic VCAR, as well as for OsiriX MD.
6. is designed to assist the user	Yes	Yes	Not specifically claimed in the Intended Use statement, but implicit in the functionality.	Same

7. in the evaluation and documentation of liver morphology,	Yes	Yes	Yes (Not specifically claimed in the Intended Use statement, but implied: General image viewing and analysis application for all patients).Yes (Not specifically claimed in the Intended Use statement, but implied: General image viewing and analysis application for all patients).	Same
8. specifically liver surface nodularity, provided that the surface nodularity is adequately depicted on the CT images.	Yes	Not specifically claimed in the Intended Use statement; Hepatic VCAR is intended for evaluating liver morphology which may include aspects of surface nodularity, but features are primarily focused on evaluation and quantitation of liver lesions, provided they are visible on the CT images.	Not specifically claimed in the Intended Use statement; OsiriX MD may be used to evaluate liver surface nodularity.	Same
9. provides quantitative metrics related to liver fibrosis	Yes	Not specifically claimed in the Intended Use statement; Hepatic VCAR is used to assess liver volumes which are in turn used to asses hepatic fibrosis.	Not specifically claimed in the Intended Use statement, but these types of measurement tools are included in the device features.	Same for secondary predicate device
10. by automating segmentation of the liver surface within user-defined Regions of Interest (ROIs)	Yes	Yes	No	Same for primary predicate device
11. and calculating distances and means related to the liver surface nodularity.	Yes	No	Not specifically claimed in the Intended Use statement, but these types of measurement tools are included in the device features.	Same for secondary predicate device
12. offers reporting capabilities for documenting user-confirmed results	Yes	Yes	Yes	Same
13. facilitating communication with other trained healthcare professionals	Yes	Yes	Not specifically claimed in the Intended Use statement, but implied by "Images and data can be...communicated."	Same
14. facilitating assessment of changes over time	Yes	Similar - See #8. Hepatic VCAR is intended to assist with evaluating changes in liver lesions over time. LSN is intended to assist with evaluating changes in liver surface nodularity over time.	Not specifically claimed in the Intended Use statement. In general, quantitative measurements facilitate assessment of morphological changes over time, so this is an implicit benefit of the device features.	Same
15. intended to provide image-related information that is interpreted by a trained professional	Yes	Yes	Yes. (Not explicitly stated, but implied).	Same
16. does not directly generate any diagnosis	Yes	Yes. (Not explicitly stated, but implied).	Yes. (Not explicitly stated, but implied).	Same
17. The information provided should not be used in isolation when making patient management decisions	Yes	Yes. (Not explicitly stated, but implied by device classification).	Yes. (Not explicitly stated, but implied by device classification).	Same
18. not intended for use with or for the diagnostic interpretation of mammography images	Yes	Yes. (Not explicitly stated for Hepatic VCAR, but implied by Volume Viewer Plus's exclusion of mammography images).	No. (allows viewing of mammography images with an appropriate monitor)	Same for primary predicate device

Subject Device Indications for Use/Intended Use Statement: LSN

LSN (Liver Surface Nodularity) is an image analysis software application intended to assist radiologists and other trained healthcare professionals in analyzing and reporting on the liver morphology depicted in computed tomography (CT) images for use in assessment of chronic liver disease. LSN is designed to assist the user in the evaluation and documentation of liver morphology, specifically liver surface nodularity, provided that the surface nodularity is adequately depicted on the CT images.

LSN provides quantitative metrics related to liver fibrosis by automating segmentation of the liver surface within user-defined Regions of Interest (ROIs) and calculating distances and means related to the liver surface nodularity. LSN also offers reporting capabilities for documenting user-confirmed results, thereby facilitating communication with other trained healthcare professionals and assessment of changes over time.

LSN is intended to provide image-related information that is interpreted by a trained professional, but it does not directly generate any diagnosis. The information provided by LSN should not be used in isolation when making patient management decisions.

LSN is not intended for use with or for the diagnostic interpretation of mammography images.

Primary Predicate Indications for Use/Intended Use Statement: Hepatic VCAR

Hepatic VCAR is a CT image analysis software package(1) that allows the analysis and visualization of Liver CT data(3,5) derived from DICOM 3.0 compliant CT scans. Hepatic VCAR is designed for the purpose of assessing liver morphology(5,7), including liver lesion, provided the lesion has different CT appearance from surrounding liver tissue; and its change over time(14) through automated tools for liver, liver lobe, liver segments and liver lesion segmentation and measurement(10). It is intended for use by clinicians(2) to process, review, archive, print and distribute(3,12,13) liver CT studies.

This software will assist the user(6) by providing initial 3D segmentation(10), vessel analysis, visualization, and quantitative analysis of liver anatomy(7). The user has the ability to adjust the contour and confirm the final segmentation(2,6).

Secondary Predicate Indications for Use/Intended Use Statement: OsiriX MD

OsiriX MD TM is a software device intended for viewing of images acquired from CT(3), MR, CR, OR,US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated(12,13), processed, and displayed(1) within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation.

For primary diagnosis(4), post process DICOM 'for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.(18) It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with the clinical application(2).

A comparison of the subject device's technical characteristics compared to the predicate devices is summarized in the following table:

Technical Characteristic	**Subject**	**Primary Predicate:** **Hepatic VCAR**	**Secondary Predicate:** **OsiriX MD**
1. Designed to work as a plug-in software application that works with an external software platform application by leveraging the external platform's DICOM communications, image display, and general image processing capabilities	Yes	Similar - Works with Volume Viewer Plus software application from GE Medical Systems (K041521) to provide liver-specific functionality, including semi-automated liver segmentation	No - OsiriX MD is the platform application that provides DICOM communications, image display, and general image processing capabilities which are leveraged by the LSN application.
2. Works with DICOM-standard CT images	Yes	Yes	Multimodality including CT
3. No special CT acquisition required	Yes	Yes	Yes
4. User-defined ROIs	Yes (leverages OsiriX ROI tools via published API)	Yes	Yes - offers support for a wide range of ROI types and statistics
5. User may accept/reject any/all ROIs before finalizing measurements and creating a report	Yes	Yes	Yes
6. Semi-automated liver boundary detection inside user-defined ROIs	Yes	Yes (ROIs may be complete images that user has identified as containing liver)	No
7. Calculates and displays smoothed liver surface approximation using a polygonal approximation to the surface	Creates and displays a smoothed polynomial (spline) from the bounding surface determined by a semi-automated edge detection based on threshold processing of 2D data	Not verified how the liver surface is extracted and and displayed, but presumably using a smooth polynomial mesh.	Yes - It is possible to perform this step manually.
8. User-customizable colors for ROI and text annotations on images	Yes	Yes	Yes

9. Average spline-to-surface distance for each ROI and overall LSN Score calculation.	Yes	No	LSN measurements for a segment of liver surface may be performed manually using native OsiriX measurement tools with off-line calculation of the overall LSN Score
10. Display output of measurement tools for user review and acceptance	Yes	Yes	Yes
11. Report generation	Yes	Yes	Yes
12. Runs on standard operating systems and hardware	Yes: macOS, commercial computers	Yes: Windows OS, commercial computers	Yes: macOS, commercial computers
Physical Characteristic			
13. Post-processing application (non-real-time, non-contacting, not life supporting or sustaining)	Yes	Yes	Yes
14. Sterilization and Shelf-life	Not applicable, software application	Not applicable, software application	Not applicable, software application
15. Biocompatibility	Not applicable, software application	Not applicable, software application	Not applicable, software application
16. Electromagnetic Compatibility and Electrical Safety	Not applicable, software application	Not applicable, software application	Not applicable, software application

The intended use and technical characteristics for LSN are similar to both predicate devices listed in the Predicate Device Information section above for a software application that provides a user interface to allow a clinician to load, display, measure, and identify regions of interests. The software algorithms calculate statistical information based on the intensities of the image pixels contained within user-identified regions of interest. The calculated values provide a clinician with relevant information for assessment of chronic liver disease.

LSN is a software-only device, is non-patient contacting, and is used by highly-trained healthcare professionals such as radiologists and medical imaging technologists. LSN does not provide any interpretation of the statistical parameters displayed to the user. The trained professional is responsible for identifying, measuring, and interpreting the images and data being displayed.

LSN and both its predicate devices are substantially equivalent in the categories of technical characteristics and features. LSN does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

Testing Information and Performance

All product specifications were verified and the overall ability of the product to meet user needs was validated. Testing was performed according to internal company procedures. Software testing and validation were conducted according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Validation test results support the conclusion that actual device performance satisfies the design intent. Testing was performed in accordance with the FDA guidance document, “General Principles of Software Validation,” issued January 11, 2002, and documentation provided as recommended by FDA’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” issued May 11, 2005. Bench testing (functional and integration) was conducted for LSN during product development.

Bench testing included functional verification to ensure software installation, licensing, labeling, and feature functionality all met design requirements. Arithmetic and report accuracy was verified and validated by comparison to alternative calculation mechanisms. And clinical operation was validated through usability testing.

Test results demonstrated that LSN output is repeatable for different CT imaging and reconstruction parameters, reproducible across different CT scanner types and vendors, and that the intra- and inter-observer measurement variability is low.

To obtain consistent output, images should be obtained at resolutions with sub-mm pixel sizes in the axial plane. LSN Score calculations depend on slice thickness, and to a lesser extent, other imaging parameters such as contrast agent presence, so the user is instructed that comparisons to previous results published in the scientific literature or between different CT exams should be undertaken with a knowledge of these dependencies.

The LSN risk analysis was completed and risk control measures were implemented to mitigate unacceptable hazards. LSN relies upon user expertise to determine the suitability of CT images for analysis. Images with excessive noise, artifacts, and/or confounding anatomy or pathology obscuring any portion of the liver surface to be analyzed should not be used. Verification and validation testing results supported the claims of substantial equivalence.

LSN has not been evaluated with images from patients of all ethnicities. It has been primarily evaluated with patients with White and Black racial backgrounds. LSN has not been evaluated with images from pediatric patients.

Design and Development Standards and Guidance

LSN was designed and developed using the following standards and guidance:

- NEMA PS 3.1-3.20: Digital Imaging and Communications in Medicine (DICOM)
- ISO 14971: Medical devices – Application of risk management to medical devices
- IEC 62304: Medical device software – Software life cycle processes
- ISO 13485: Medical devices – Quality management systems
- FDA: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- FDA: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- FDA: Off-The-Shelf Software Use in Medical Devices

Conclusion

LSN has the same intended use as the primary and secondary predicate devices as an image processing software application for DICOM-format CT images. There is significant overlap between LSN and the predicate devices in technological characteristics. Any differences between LSN and the predicate devices do not raise new or different questions of safety and effectiveness. The result of all testing conducted was found acceptable to support the claim of substantial equivalence.