Synapsica
℅ Rory Carrillo
Quality & Regulatory Consultant
Cosm
45 Bartlett Street, Unit 706
SAN FRANCISCO CA 94110

March 28, 2023

Re: K222174
Trade/Device Name: RadioLens v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: February 17, 2023
Received: February 21, 2023

Dear Rory Carrillo:

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 and Part 809); 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,

Jessica Lamb, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222174

Device Name
RadioLens v1.0

Indications for Use *(Describe)*
RadioLens v1.0 software is a medical diagnostic application that displays, processes, stores, and transfers DICOM data, with the exception of mammography. It provides the capability to store images and patient information, perform filtering, digital manipulation, and quantitative measurements. The client software is designed to run on standard personal and business computers.

RadioLens v1.0 includes an optional SpindleX module which is used to analyze potential vertebral body displacements in spine, either absolute or relative, using cervical/lumbar digital X-Rays of spine. A qualified medical practitioner may use the module to semi-automatically identify relevant spine anatomy and calculate vertebral displacement measurements. Measurements are then used to determine severity and location of any spinal ligament injury leading to subluxation using criteria published in AMA Guides to The Evaluation of Permanent Impairment, 5th & 6th edition.

SpindleX is meant for assistance with analysis of spinal ligament injury in the adult population (>18 years of age) as captured in stress x-rays. SpindleX is not meant for patients that have undergone surgery or other traumatic injury that result in distortion of spinal anatomy.

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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Section 5. 510(k) Summary

1. General Information

510(k) Sponsor	Synapsica Healthcare, Inc.
Address	2591 Dallas Parkway Suite 300 Frisco, TX 75034
Correspondence Person	Rory A. Carrillo Regulatory Consultant | Cosm
Contact Information	Email: rory@cosmhq.com Phone: (562) 533-7010
Date Prepared	July 22, 2022

2. Subject Device

Proprietary Name	RadioLens v1.0
Common Name	RadioLens v1.0
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QIH
Regulatory Class	II

3. Predicate Device

Proprietary Name	Spine CAMP™
Premarket Notification	K221632
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QIH
Regulatory Class	II

4. Device Description

RadioLens v1.0 is a medical image management and processing system for general human radiology reporting and provides a browser based interface for transfer of DICOM files from the scanning equipment to Synapsica's cloud server, for distribution to authorized users, including Radiologists. It also provides a worklist that keeps track of patient cases that the user needs to work on; a DICOM Viewer that allows users to view and analyze images in patient scan; and a report editor where the Radiologist can prepare the text report that goes back to the patient and referring provider.

RadioLens v1.0 includes an optional SpindleX module. The SpindleX is an artificial intelligence (AI) module that works on digital stress x-rays of the spine and assists with clinical interpretation

by a qualified Radiologist by automatically providing multiple relevant measurements in the spine.

SpindleX is meant for assistance with analysis of spinal ligament injury in the adult population (>18 years of age) as captured in stress x-rays. SpindleX is not meant for patients that have undergone surgery or other traumatic injury that result in distortion of spinal anatomy.

The following visualization, quantification, and reporting functionalities are provided by the software:

Visualization

- 2D image review
- Image navigation tools
- Patient worklist

Quantitative Analysis

The subject device performs the following anatomical measurements:

- Ruth Jackson's angle,
- Ferguson's angle
- Canal diameter
- Displacement of L3 vertebrae
- Vertebral offset
- Motion Segment Integrity, Translational & Angular

Reporting

The subject device provides a detailed, objective report for stress x-rays of spine following standards set by American Medical Association (AMA). The report is pre-populated with annotated snapshots of digital x-ray scan of the spine generated by SpindleX. Relevant measurements, per the Quantitative Analysis discussed above, are provided along the annotated images. Once the report has been edited and finalized by the Radiologist, it can be downloaded in microsoft word or pdf format.

Algorithm Training

The RadioLens SpindleX module was trained on 13,452 cervical and 6,492 lumbar retrospective studies that were de-identified and did not contain any PHI. The data was sourced from over 200 institutions across the U.S., making the dataset very diverse and representative of the population demographic. These studies consisted of images of stress x-rays of cervical and lumbar spine of adults (>18 years) taken in the neutral, flexion or extension positions where the patient's body is either tilting down or up respectively. Training dataset did not include scans of patients that have undergone surgeries or any other traumatic injury that results in distortion of anatomy. These images had morphometry points pre-marked on cervical and lumbar images by US board certified Radiologists who used these to prepare clinical reports that were delivered to patients. These pre-marked points were treated as ground truth for training of models

5. Indications for Use

The RadioLens v1.0 software is a medical diagnostic application that displays, processes, stores, and transfers DICOM data, with the exception of mammography. It provides the capability to store images and patient information, perform filtering, digital manipulation, and quantitative measurements. The client software is designed to run on standard personal and business computers.

RadioLens v1.0 includes an optional SpindleX module which is used to analyze potential vertebral body displacements in spine, either absolute or relative, using cervical/lumbar digital X-Rays of spine. A qualified medical practitioner may use the module to semi-automatically identify relevant spine anatomy and calculate vertebral displacement measurements. Measurements are then used to determine severity and location of any spinal ligament injury leading to subluxation using criteria published in AMA Guides to The Evaluation of Permanent Impairment, 5th & 6th edition.

SpindleX is meant for assistance with analysis of spinal ligament injury in the adult population (>18 years of age) as captured in stress x-rays. SpindleX is not meant for patients that have undergone surgery or other traumatic injury that result in distortion of spinal anatomy.

6. Comparison of Technological Characteristics with Predicate Device

Feature/ Function	**Subject Device:** RadioLens v1.0	**Predicate Device:** Spine CAMP™ (K221632)
Intended Users	Qualified medical practitioners	Radiologists
Intended Environment	Clinical settings	Clinical settings
Device Class	II	II
Image Input	DICOM	DICOM
Image Display	Static	Static
Anatomical Area	Spine	Spine
Body Part Detection	Yes, only through the optional SpindleX module (Cervical, Lumbar and others for digital x-rays of spine)	No
Body Position Detection	Yes, only through the optional SpindleX module (Flexion, extension or neutral)	N/A

Feature/ Function	Subject Device: RadioLens v1.0	Predicate Device: Spine CAMP™ (K221632)
Quantitative Analysis	Only through the optional SpindleX module the following measurements are provided: - Ruth Jackson's angle - Ferguson's angle - Canal diameter - Displacement of L3 vertebrae - Vertebral offset - Motion Segment Integrity, Translational & Angular	- Linear measurements - Angular measurements - Vertebral body detection - Vertebral body landmark specification - Vertebral body registration
2D Motion Analysis	N/A	Yes
Image Registration	N/A	Yes
Report Creation	Yes	Yes

The subject device and predicate device have substantially equivalent indications for use and technological characteristics. The minor differences do not raise questions of safety or effectiveness as the underlying technology is similar and risks associated with these differences are mitigated with similar general and special controls.

7. Performance Data

Safety and performance of the RadioLens v1.0 has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with *ANSI AAMI IEC 62304:2006/A1:2016 - Medical device software – Software life cycle processes,* in addition to the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices."*

A multi-reader multi-center (MRMC) retrospective study was carried out in the United States involving a sample size of 600 de-identified stress x-rays (300 cervical and 300 lumbar) collected from over 200 institutions where each case has flexion, extension, and neutral positions of the spine. The data collected for clinical assessment was independent from the data used for training. Three (3) expert radiologists analyzed each case with and without the SpindleX module and sensitivity, specificity, and/or agreement was used to compare performance. The following outline the results of the assessment:

- For identification of body part among cervical and lumbar scans, the model had 100% sensitivity for the scans used in the validation study. This was against a target sensitivity of 95%.
- For identification of patient position among flexion, extension and neutral the model had 96.8%, 92.0%, and 90.5% sensitivities respectively. This was against a target sensitivity of 90% in each category.
- For prediction of measurements by the model, the pass criterion was for the combined ICC scores of the model with 3 expert radiologists needed to be as good as ICC scores among those radiologists alone. In the validation exercise, we observed that model agreement was equivalent to agreement that radiologists had among themselves.

  For this purpose, ICC scores were categorized as follows:

  1. *< 0.5 - Poor*
  2. *0.5 - 0.75 - Moderate*
  3. *0.75 - 0.9 - Good*
  4. *> 0.9 - Excellent*

  The following tables capture the aided versus unaided agreement:

CERVICAL		
Measurement for pathology	**Radiologists ICC**	**Rads & Model ICC**
Stress Lines (degrees)	0.957 (E)	0.953 (E)
Canal Diameter (mm)	0.950 (E)	0.955 (E)
Vertebral Offset Neutral (mm)	0.698 (M)	0.707 (M)
Angular MSI (degrees)	0.769 (G)	0.781 (G)
Translational Motion 5th Edition (mm)	0.712 (M)	0.717 (M)
Translational Motion 6th Edition - Flexion (mm)	0.793 (G)	0.802 (G)
Translational Motion 6th Edition - Extension (mm)	0.707 (M)	0.716 (M)

LUMBAR		
Measurement for pathology	**Radiologists ICC**	**Rads & Model ICC**
Stress Lines (degrees)	0.979 (E)	0.968 (E)

LUMBAR		
Measurement for pathology	**Radiologists ICC**	**Rads & Model ICC**
Canal Diameter (mm)	0.826 (G)	0.784 (G)
Ferguson's Angle (degrees)	0.968 (E)	0.939 (E)
Integrity of 3rd Lumbar Vertebra (mm)	0.997 (E)	0.996 (E)
Vertebral Offset Neutral (mm)	0.820 (G)	0.777 (G)
Angular MSI (degrees)	0.792 (G)	0.771 (G)
Translational Motion 5th Edition (mm)	0.710 (M)	0.656 (M)
Translational Motion 6th Edition - Flexion (mm)	0.809 (G)	0.774 (G)
Translational Motion 6th Edition - Extension (mm)	0.823 (G)	0.769 (G)

Rater Agreement Legend: P - Poor, M - Moderate, G - Good, E - Excellent

8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the RadioLens v1.0 raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety and effectiveness.