Lexi Co., Ltd.
% Takao Kusunoki
Regulatory Affairs
2-11-1 Sugamo, Toshima-Ku
Tokyo, 170-0002
JAPAN

May 27, 2021

Re: K200704
Trade/Device Name: ZedView ver.14.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 26, 2021
Received: April 28, 2021

Dear Takao Kusunoki:

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

Indications for Use

510(k) Number (if known): K200704

Device Name: ZedView ver.14.0

Indications for Use:

ZedView is indicated for pre-operative planning and post-operative evaluations for various surgical procedures such as artificial joint replacement (arthroplasty), osteotomy, trauma, deformity correction.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 6: Traditional 510(k) Summary

6.1 Submitter

Date Prepared: Feburary 24, 2020

Traditional 510(k) Owner/Applicant: LEXI Co., Ltd.
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Toshima-ku, Tokyo, 170-0002, JAPAN
Tel: +81-03-5394-4833

Contact Person: Takao Kusunoki
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Official Correspondent: Same as above

6.2 Device Identification

Trade Name:	ZedView ver.14.0
Common Name:	Image Management System
Review Panel:	Radiology
Classification Name:	Medical Image Management and Processing System
Device Class:	2
Product Code:	LLZ
Regulation Number	21 CFR 892.2050

6.3 Predicate Devices

Trade Name:	ZedView
Manufacturer:	LEXI CO., LTD.
Reference:	K133022

6.4 Device Description

ZedView is a software package that provides computer-assisted 3D planning and evaluations using 2D image data in DICOM or other formats, for various pre-operative surgical procedures and post-operative evaluations. The software is composed of various modules described below.

- **ZedViewDB**

ZedViewDB application module basically deals with database management of 2D slice image data (DICOM images) imported into the software, viewing of data parameters, and ZedView3D project management. The module also provides functions for communication of image data and planned reports in DICOM format to PACS.

- **ZedView3D**

ZedView3D application module basically provides a workspace (or project) for preparing a pre-operative plan using functions for 3D visualization, measurement, simulations, templating, etc. Based on functionalities and the intended use, ZedView3D is further categorized into the following specialized functional modules.

  - **ZedEdit**

ZedEdit basically deals with 2D image adjustment and analysis, 3D model reconstruction (surface and volume rendering) and model operations, 2D and 3D measurements, and export of 3D polygon data in various formats (STL, DXF, PLY, AVI, etc.)

  - **ZedHip**

ZedHip deals with pre-operative planning for hip arthroplasty by providing automated 3D model generation, 3D simulations and measurements, and computation of various useful surgical parameters calculated in simulated environments using CT (Computed Tomography) data. The module allows users to work out a pre-operative plan by loading the implants (stem and cup) of various types and sizes onto the reconstructed 3D bone models and by simulating and determining the optimal implants, alignment positions and amount and lines of resection.

  - **ZedHip2.5D**

ZedHip2.5D deals with pre-operative planning for hip arthroplasty by providing simulations and measurements, and computation of various useful surgical parameters calculated in simulated environments using CR (Computed Radiography) or digital X-ray(DX) data.

  - **ZedKnee/JIGEN**

ZedKnee/JIGEN deals with pre-operative planning for knee arthroplasty by providing automated 3D model generation and 3D simulations and measurements, and computation of various useful surgical parameters calculated in simulated environments. The module allows users to work out a pre-operative plan by loading the implants (femur and tibia components), intramedullary (IM) rods of various types and sizes and surgical jigs onto the reconstructed 3D bone models and by simulating and determining the optimal implants, alignment positions and amount and lines of resection.

  - **ZedKnee2.5D**

ZedKnee2.5D deals with pre-operative planning for knee arthroplasty by providing simulations and measurements, and computation of various useful surgical parameters calculated in simulated environments using CR (Computed Radiography) or digital X-ray(DX) data.

  - **ZedOsteotomy**

ZedOsteotomy specializes in pre-operative planning for Osteotomy by providing automated 3D model generation, 3D simulations and measurements, and computation of various useful surgical parameters calculated in simulated environments using CT (Computed Tomography) data. The module provides tools for simulation and determination of correct position for segmentation of reconstructed 3D bone models (pelvic acetabulum) and of correct alignment for segmented bones.

  - **ZedHTO**

ZedHTO specializes in pre-operative planning for High Tibial Osteotomy by providing automated 3D model generation, 3D simulations and measurements, and computation of various useful surgical parameters calculated in simulated environments using CT (Computed Tomography)

data. The module provides tools for simulation and determination of correct position for segmentation of reconstructed 3D tibial bone model and of correct alignment for segmented bones.

- **ZedSpine**

ZedSpine deals with pre-operative planning for spinal fusion surgery and scoliosis surgery by providing 3D simulations and measurements and computation of useful surgical parameters calculated in simulated environments using CT(Computed Tomography) data.

- **ZedTrauma**

ZedTrauma deals with pre-operative planning for trauma surgery by providing 3D simulations and measurements and computation of useful surgical parameters calculated in simulated environments using CT (Computed Tomography) data.

- **ZedShoulder**

ZedShoulder deals with pre-operative planning for shoulder arthroplasty by providing automated 3D model generation, 3D simulations and measurements, and computation of various useful surgical parameters calculated in simulated environments using CT (Computed Tomography) data. The module allows users to work out a pre-operative plan by loading the implants (glenoid and stem) of various types and sizes onto the reconstructed 3D bone models and by simulating and determining the optimal implants, alignment positions and amount and lines of resection.

- **ZedReport**

ZedReport application module basically serves as editor for creating, editing, exporting and transmitting of ZedView3D screenshot reports. The reports are prepared by adding and editing the DICOM multi-frame screenshots captured from ZedView3D application during pre-operative planning, with patient information and various notes attached together. The module also provides functions for directly uploading the prepared reports to PACS servers or printing the reports in paper, to allow surgeons to refer to the planned reports during surgery.

Besides the regular (software package) version that requires to be installed in the user's PC, a web-based planning-service version (ZedPlanning) will also be available. The planning-service version will have a web-based interface as front-end and will not require any installations.

6.5 Indications for Use Statement

ZedView is indicated for pre-operative planning and post-operative evaluations for various surgical procedures such as artificial joint replacement (arthroplasty), osteotomy, trauma, deformity correction.

Comment:
Although Indications for Use has been changed as follows from the last time, we believe that the all points are minor.

1) The phrases "post-operative evaluations" has been added.

The optional function of post-operative evaluation added to ZedHip, ZedKnee and ZedShoulder modules enables surgeons to assess the position of the implant. This function does not have clinical hazards.

2) The phrases "related to hip and knee" has been removed
The target site of ZedView has been expanded using the same structures and functions

3) The phrases "osteotomy, trauma and deformity correction" has been added.
Pre-operative planning of these procedures has been incorporated in ZedView by amplified existing functions.

6.6 Comparison of Technological Characteristics

ZedView ver.14.0 is substantially equivalent to ZedView (K133022). Both ZedView ver.14.0 and ZedView have similar device specifications and bench testing.

Table 6-1: *Comparison of Subject and Predicate Devices*

	Predicate Device ZedView	**This Time ZedView ver.14.0**
510(k)	K133022	-
Classification	II	II
Intended Use	ZedView is intended to be used to assist qualified medical professionals to perform fast and effective pre-operative planning for various surgical procedures related to hip and knee by using 2D image data. The software is basically intended to be standalone, however some part of the software provides features for communicating with PACS servers to acquire the CT data of various patients or to upload planned projects, images or reports to the servers. The software primarily provides import and storage of CT images of various patients in DICOM or other formats and provides a means of 3D templating of implants and positioning of fixation devices by calculating surgical parameters in simulated environments and performing 3D measurements on each pre-operative patient data using 2D image viewing and manipulations, 3D visualizations and various MPR (Multi-Planar Reconstruction)	ZedView is intended to be used to assist qualified medical professionals (surgeons, planners) to perform fast and effective pre-operative planning and post-operative evaluations for various surgical procedures by using 2D image data. The software is basically intended to be standalone, however some part of the software provides features for communicating with PACS servers to acquire the CT data of various patients or to upload planned projects, images or reports to the servers. The software primarily provides import and storage of CT images of various patients in DICOM or other formats. Also, it provides a means of 3D templating of implants and positioning of fixation devices by calculating surgical parameters in simulated environments and performing 3D measurements on each pre-operative patient data, using 2D image viewing and manipulations, 3D visualizations and various MPR (Multi-Planar

	functions. The software also provides separate modules that support pre-operative planning of hip and knee arthroplasty for 2D digital X-ray images obtained with the EOS imaging system by providing quasi-3D templating, 3D measurement, etc. Besides the functional modules for artificial joint replacement surgeries, the software also provides a module that incorporates planning and evaluations for osteotomy (Curved Periacetabular Osteotomy etc.).	Reconstruction) functions. Besides the functional modules for artificial joint replacement surgeries, the software also provides a module that incorporates planning and evaluations for osteotomy (Curved Periacetabular Osteotomy etc.). Although the software is intended to be used for pre-operative planning purposes, it does not drive other medical devices such as jigs and implantable components, or influence the use of such medical devices in ways that would increase the risk associated with the planning. The software is intended to be used only for assisting surgeons in making faster and effective plans.
Indications for Use	Pre-operative planning for various surgical procedures related to hip and knee like artificial joint replacement (3D templating of implants), osteotomy	ZedView is indicated for pre-operative planning and post-operative evaluations for various surgical procedures such as artificial joint replacement (arthroplasty), osteotomy, trauma, deformity correction.
Target Site	Hip and Knee	Hip, Knee, Shoulder and Spine
Operating System	Windows	Same
Availability of Device	Can be configured to be launched from within a workstation environment or as a standalone PC application for planning orthopedic procedures.	Same
Source of images	Receive digital images from various sources (including PACS system)	Same
Patient contact	None	Same
Control of life-sustaining devices	None	Same
Human intervention for interpretation of images	Required	Same
Ability to add additional modules when available	Yes	Same

6.7 Non-Clinical Performance Test Summary

Safety of ZedView ver.14.0 is demonstrated through the conducted safety tests. ZedView ver.14.0 is in compliance with the following safety standards:

- 12-300 NEMA PS 3.1-3.20 (2016) (**Appendix I**)

In addition, the results of the non-clinical performance tests demonstrate that ZedView ver.14.0 is substantially equivalent to the predicate devices.

6.8 Clinical Performance Test Summary

None.

6.9 Statement of Substantial Equivalence

While there are some differences between ZedView ver.14.0 and its predicate device, these differences are minor and do not affect device substantial equivalence. ZedView ver.14.0 has the same basic operational principles and technical characteristics as its predicate device and it functions in the same manner. Additionally, it has the almost same indications for use and intended function and use and is as safe, as effective, and performs as well as or better than its predicate device. Therefore, LEXI believes that ZedView ver.14.0 is substantially equivalent to the predicate device cited within this submission.