IB Lab GmbH
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

November 5, 2019

Re: K192109
Trade/Device Name: KOALA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: October 11, 2019
Received: October 11, 2019

Dear Dr. Smith:

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)*
K192109

Device Name
KOALA

Indications for Use *(Describe)*
IB Lab KOALA is a radiological fully-automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the measurement of minimum joint space width; the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren & Lawrence Grading of standing, fixed-flexion radiographs of the knee. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, radiologists, orthopedics, physicians and medical technicians.

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
IB Lab's KOALA

K192109

Submitter

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1130 Vienna, Austria
Phone: +43 1 9051206
Contact Person: Dr. Richard Ljuhar
Date Prepared: October 11, 2019

Name of Device: KOALA
Classification Name: Picture archiving and communications system (21 C.F.R. 892.2050)
Regulatory Class: Class II
Product Code: LLZ/892.2050, JAK/892.1750

Predicate Device: Ortho Kinematics, Inc.'s VMA™ System version 3.0 (K172327)

Reference Device: Zebra Medical Vision Ltd.'s HealthCCS (K172983)

Device Description

The Knee OsteoArthritis Labeling Assistant (KOALA) software provides metric measurements of the joint space width and indicators for presence or absence of radiographic features of osteoarthritis (OA) on posterior-anterior or anterior-posterior (PA/AP) knee X-ray images. The outputs aid clinical professionals who are interested in the analysis of knee OA in adult patients, either suffering from knee OA or having an elevated risk of developing the disease.

Outputs are summarized in a KOALA report that can be viewed on any FDA approved DICOM viewer workstation. KOALA operates in a Linux environment and can be deployed to be compatible with any operating system supporting the third-party software Docker. The integration environment has to support KOALA data input and output requirements. The device does not interact with the patient directly, nor does it control any life-sustaining devices.

Intended Use / Indications for Use

IB Lab KOALA is a radiological fully-automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the measurement of minimum joint space width; the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren & Lawrence Grading of standing, fixed-flexion radiographs of the knee. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, radiologists, orthopedics, physicians and medical technicians.

Summary of Technological Characteristics

The following technological similarities and differences exist between the subject and predicate devices. The predicate and subject software utilize computer vision and machine learning algorithms trained on medical images. The machine-learning algorithms allow for high accuracy in the detection and measurement of OA related symptoms visible on knee radiographs.

A table comparing the key features of the subject and predicate devices is provided below.

Feature	IB Lab's KOALA Software (Subject Device)	Ortho Kinematics, Inc.'s VMA System (K172327, Predicate Device)	Zebra Medical Vision Ltd.'s HealthCCS Software (K172983, Reference Device)
Classification Name and Product Code	System, Image Processing, Radiological (LLZ)	System, Image Processing, Radiological (LLZ)	Computed Tomography X-Ray System (JAK)
Runs on Server	Yes	Yes	Yes
Image Input	DICOM compliant images collected in other devices in either digitally computed (CR) or directly digital (DX) formats	DICOM compliant images inputted from cleared PACS	DICOM
Anatomical Area	Joint (knee)	Spine	Heart (coronary artery)
Image Processing	Knee detection; Landmark detection; Joint space detection	Semi-automated vertebral body templating and tracking	Calcification location marking
Measurements	Yes	Yes	Yes
Grading based on measurements	Yes, cutoffs on grades	No	Yes
Human Intervention for interpretation	Required	Required	Required
Intended User	Trained professionals	Physicians and clinical professionals	Health care professionals

Performance Data

Software verification and validation testing was completed for the subject device. The software functioned as intended and all results observed were as expected.

The company performed standalone clinical performance validation on a dataset of images from a large longitudinal US study, Osteoarthritis Initiative (OAI) study. This dataset contained a total of 6597 radiographs, representing 1149 individuals for which ground truth grading for Kellgren

Lawrence grades, as well as osteophyte, sclerosis and joint space narrowing grades according to the OARSI (Osteoarthritis Research Society International) guidelines, was established by three physicians following adjudication procedures for discrepancies.

The quality of the joint space width (JSW) measurements was quantified by orthogonal linear regression against reference measurements. The performance of the indicators was assessed by calculating its accuracy matrix (confusion matrix) against the reference standard and calculating sensitivity and specificity.

The status indicator outputs of KOALA performed as follows

Status Indicator	Sensitivity (95% CI)	Specificity (95% CI)
Kellgren-Lawrence status (KL ≥ 2)	0.87 (0.84, 0.9)	0.83 (0.8, 0.86)
Joint Space Narrowing Status (JSN OARSI grade > 0)	0.83 (0.8, 0.86)	0.8 (0.76, 0.83)
Osteophytosis status (Ost OARSI grade > 0)	0.86 (0.81, 0.9)	0.79 (0.76, 0.83)
Sclerosis status (Scl OARSI grade > 0)	0.82 (0.8, 0.87)	0.8 (0.76, 0.83)

In addition, the accuracy of the joint space width measurements was compared to equivalent measurements also provided as part of the outputs from the longitudinal study mentioned above, using orthogonal linear regressions.

	Slope	Intercept [mm]
Medial	1.02 (0.99 ; 1.05)	-0.08 (-0.22 ; 0.03)
Lateral	0.97 (0.93 ; 1.00)	0.08 (-0.15 ; 0.30)

The analysis supports good agreement between the two sets of measurements.

In summary, performance validation data establish that KOALA is an effective image processing device that provides reliable measurements and accurate indicators for presence/absence of radiographic features relevant for the diagnosis and classification of osteoarthritis. Thus, the device performs as intended and is substantially equivalent to the predicate device.

Conclusions

KOALA is as safe and effective as the predicate device. The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences between subject and predicate device in indications do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when used as labeled. Performance data demonstrate that the device performs as intended. Thus, KOALA is substantially equivalent.